School of Nursing, Midwifery and Paramedicine

An Exploratory Study of Health Care Providers' Acceptance of Opt-Out HIV Testing in Western Australia

Stacy Ann Leidel

This thesis is presented for the degree of
Doctor of Philosophy
of
Curtin University

June 2017

DECLARATION

To the best of my knowledge this thesis contains no material previously published by any other person except where due acknowledgment has been made. This thesis contains no material which has been accepted for the award of any other degree or diploma in any university.

Signed: Dated: 20 May 2017

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ACKNOWLEDGEMENTS

Firstly, I would like to express my gratitude to the nurses and doctors at Homeless Healthcare for their support for this project. Not only were they willing to try this new approach to patient care, they became champions for opt-out HIV testing. I especially appreciate that they offered their time (often at odd hours) to be interviewed. I thank Dr Andrew Davies for his assistance with board of directors' approval, encouraging staff to participate in the project, and revising the final manuscript.

I would like to thank my primary supervisor, Professor Gavin Leslie, for agreeing to supervise me midway through the project. I would not have finished this thesis without his willingness to supervise me after I moved back to the US. Professor Leslie generously gave up many of his evenings for our fortnightly Skype meetings. These discussions greatly enriched my PhD experience and made me a better writer and researcher. Professor Leslie's experience as a journal editor was extremely valuable in the writing and editing processes.

I would also like to acknowledge the contributions of my thesis committee members, Professor Duncan Boldy and Associate Professor Sonya Girdler. Professor Boldy encouraged me to do a PhD, helped me develop my ideas into research questions, and provided useful advice throughout the project. Associate Professor Sonya Girdler offered valuable insights into the research design and analysis. I am grateful for her suggestions on many drafts and especially for assisting me with the final paper via Skype.

I thank the other researchers and clinicians who were always ready to lend a hand. Professor Jaya Dantas, Director of Graduate Studies was always encouraging and supportive. Dr Sally Wilson's expertise with systematic reviews was immensely helpful. Working with Dr Wilson greatly enhanced my research skills. I also thank Dr Ruth McConigley for her assistance with research design and manuscript development in the initial stages of the thesis. I am indebted to Leah Williams, nurse practitioner from the Royal Perth Hospital HIV service, who spent hours sharing her HIV expertise with me as I developed the research project. She provided valuable guidance for the development of the linkage to care protocol.

This research would not have been possible without support from the Australian Postgraduate Award which allowed me to focus exclusively on the thesis for nearly a year. The APA support helped me establish momentum that sustained me through the last year and a half of the project.

I would like to express my gratitude to the thousands of patients I have cared for during my 15 years as a nurse practitioner. Without my clinical experiences, I could never

have envisioned this research project. In 2010, I diagnosed a young woman with HIV who had presented for a routine acute complaint. She did not have typical risk factors for HIV, but because of opt-out testing, she is living a healthy and fulfilling life. This experience had a profound impact on me and eventually led to the idea for this research.

Finally, I would like to thank my husband Ross and our children Eva and Will for their unwavering love and support throughout this project. My parents, Jim and Alice Leidel, raised me to value education and to be a lifelong learner, for which I am very grateful.

ABSTRACT

Opt-out testing is a method for detecting disease in which patients are informed that they will be tested for a health condition unless they decline. Opt-out testing for HIV has been advocated as a strategy to increase the number of people who know their HIV status, enabling earlier diagnosis and management. This thesis presents the first documented exploration of opt-out HIV testing in Australia.

A mixed-methods exploratory design was developed for this study. The overarching conceptual framework was Implementation Science, the process of translating research evidence into clinical practice. The research project commenced with an assessment of the need for a change in Australian HIV testing policy through a review of international and Australian evidence. A systematic review of international qualitative research on opt-out HIV testing was then undertaken to synthesise existing evidence and develop new themes. Next, following institutional review board approvals, a qualitative study analysing health care providers' beliefs about opt-out HIV testing was conducted. Content analysis was used to develop themes from the interview data. This analysis then informed the development of a theoretical framework to guide implementation and evaluation of an opt-out HIV testing program. Finally, a prospective, mixed-methods trial was conducted to evaluate the effect of the opt-out approach on HIV testing rates in a primary health care service after the introduction of opt-out testing. The observational part of the study compared HIV testing rates between usual practice (opt-*in* testing) and opt-out testing. Finally, health care providers' experiences with opt-out HIV testing were explored through interviews guided by the theoretical framework and cross-referenced with the findings on testing rates.

The needs assessment identified a recent increase in HIV diagnoses in Australia, supporting a possible change in testing strategy. *Attitudes* and *Systems* were the main themes arising from the systematic review of international health care providers' beliefs about opt-out HIV testing. *Attitudes* captured health care providers' beliefs about opt-out HIV testing, and *Systems* referred to the operational barriers and facilitators to the implementation of opt-out HIV testing programs. In the qualitative study, 23 physicians and nurse practitioners were interviewed about their views on opt-out HIV testing. Health care providers' beliefs about HIV testing were dichotomous: HIV testing should be treated as a "normal" practice (through the opt-out approach) or an "exceptional" practice (through risk factor-based testing). Insights from this qualitative study led to the development of a comprehensive theoretical framework (integrating the Health Belief Model, Behavioural Economics, and

Normalisation Process Theory) for the implementation and evaluation of an opt-out HIV testing program. In the trial of opt-out HIV testing, testing rates were similar between usual practice (315 tests per year) and opt-out HIV testing (344 tests per year), suggesting that few patients opted out. In interviews following the trial, the participating health care providers found the opt-out approach to be acceptable.

Health care services in Australia that have not considered opt-out HIV testing now have evidence that the approach may be easily implemented and acceptable to health care providers. *Attitudes* and *Systems* affected acceptability and implementation of opt-out HIV testing in all phases of the research. The theoretical framework developed for implementation and evaluation of the opt-out HIV testing trial can be used to guide development of other opt-out testing programs both locally and internationally. Findings from this thesis form an initial evidence base for opt-out HIV testing in Australia that can underpin future clinical practice, research and policy.

LIST OF PUBLICATIONS

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Leidel, S., McConigley, R., Boldy, D., Girdler, S., & Wilson, S. (2015). Should Australia consider opt-out HIV testing? *Australasian Medical Journal 8*(1), 30-32. doi:10.4066/AMJ.2015.2290

Leidel, S., Wilson, S., McConigley, R., Boldy, D., & Girdler, S. (2015). Health-care providers' experiences with opt-out HIV testing: a systematic review. *AIDS Care, 27*(12), 1455-1467. *doi:10.1080/09540121.2015.1058895*

Leidel, S., McConigley, R., Boldy, D., Wilson, S., & Girdler, S. (2015). Australian health care providers' views on opt-out HIV testing. *BMC Public Health, 15*, 888. doi:10.1186/s12889-015-2229-9

Leidel, S., Leslie, G., Boldy, D., & Girdler, S. (2016). A comprehensive theoretical framework for the implementation and evaluation of opt-out HIV testing. *Journal of Evaluation in Clinical Practice. doi:10.1111/jep.12602*

Leidel, S., Leslie, G., Boldy, D., & Girdler, S. (2017). "We didn't have to dance around it:" opt-out HIV testing among homeless and marginalised patients. *Australian Journal of Primary Health*. doi: 10.1071/PY16120

STATEMENTS OF CONTRIBUTION BY OTHERS

Statement of Authorship

Title: **A comprehensive theoretical framework for the implementation and evaluation of opt-out HIV testing**

Citation details: Leidel, S., Leslie, G., Boldy, D., & Girdler, S. (2016). A comprehensive theoretical framework for the implementation and evaluation of opt-out HIV testing. J Eval Clin Pract. 2016; DOI:10.1111/jep.12602.

Status: Published in *Journal of Evaluation in Clinical Practice*

I, Stacy Leidel, developed the concepts and authored the above manuscript with support and assistance from the co-authors.

Stacy Leidel

10/09/2016

As a co-author, I endorse that the level of contribution by the candidate indicated above is true and appropriate.

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Prof Duncan Boldy		1.05.2017
Assoc Prof Sonya Girdler		26.04.17

Statement of Authorship

Title: Australian health care providers' views on opt-out HIV testing

Citation details: Leidel S, McConigley R, Boldy D, Wilson S, Girdler S. Australian health care providers' views on opt-out HIV testing. BMC Pub Hlth. 2015; 15:888. DOI:10.1186/s12889-015-2229-9.

Status: Published in *BMC Public Health*

I, Stacy Leidel, designed and conducted the study, analysed the results and authored the above manuscript with support and assistance from the co-authors.

Stacy Leidel

10/09/2016

As a co-author, I endorse that the level of contribution by the candidate indicated above is true and appropriate.

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Assoc Prof Sonya Girdler		26.04.17.
Dr Sally Wilson		26/04/17.

Statement of Authorship

Title: Health-care providers' experiences with opt-out HIV testing: a systematic review

Citation details: Leidel S, Wilson S, McConigley R, Boldy D, Girdler S. (2015): Health-care providers' experiences with opt-out HIV testing: a systematic review, AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV, DOI: 10.1080/09540121.2015.1058895

Status: Published in *AIDS Care*

I, Stacy Leidel, conducted the searches, analysed the results and authored the above manuscript with support and assistance from the co-authors.

Stacy Leidel

10/09/2016

As a co-author, I endorse that the level of contribution by the candidate indicated above is true and appropriate.

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Dr Ruth McConigley		20.10.16
Prof Duncan Boldy		1.5.2017
Assoc Prof Sonya Girdler		26.04.17.

5.

Statement of Authorship

Title: Should Australia consider opt-out HIV testing?

Citation details: Leidel S, McConigley R, Boldy D, Girdler S, Wilson S. Should Australia consider opt-out HIV testing? AMJ 2015;8(1):30–32. Doi:10.4066/AMJ.2015.2290

Status: Published in *Australasian Medical Journal*

I, Stacy Leidel, authored the above manuscript with support and assistance from the co-authors.

Stacy Leidel

10/09/2016

As a co-author, I endorse that the level of contribution by the candidate indicated above is true and appropriate.

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Dr Ruth McConigley		20.10.16
Prof Duncan Boldy		2.5.17
Assoc Prof Sonya Girdler		26/04/17

Statement of Authorship

Title: **"We didn't have to dance around it": opt-out HIV testing among homeless and marginalised patients**

Citation details: Leidel, S., Leslie, G., Boldy, D., Davies, A., & Girdler, S. (2017). "We didn't have to dance around it": opt-out HIV testing among homeless and marginalised patients.

Status: Published in *Australian Journal of Primary Health*. DOI: 10.1071/PY16120

I, Stacy Leidel, designed and conducted the study, analysed the results and authored the above manuscript with support and assistance from the co-authors.

Stacy Leidel

23/04/17

As a co-author, I endorse that the level of contribution by the candidate indicated above is true and appropriate.

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CHAPTER 1

INTRODUCTION

Since the world first became aware of acquired immune deficiency syndrome (AIDS) in the early 1980s, HIV/AIDS has killed 35 million people worldwide (Joint United Nations Programme on HIV/AIDS (UNAIDS), 2016). Life expectancy in many countries has decreased because of HIV (particularly in the developing world) because most deaths occur in people between the ages of 15 and 49, the prime childbearing years (Bloom, 2011). Today there are 36.7 million people living with HIV, of whom only 17 million are on life-saving anti-retroviral medications. In 2015, there were 2.1 million new HIV infections and 1.1 million deaths from AIDS (UNAIDS, 2016).

Although the story of the HIV epidemic is replete with tragedy and despair, it is also alive with human progress and hope. Despite the grim statistics, the HIV epidemic has produced some of the greatest scientific achievements of the late 20th and early 21st centuries. Within just 30 years, scientists identified the virus, mapped its genome and phylogenetic origin, developed laboratory tests, ensured the safety of blood supplies, and developed numerous drugs to treat the infection (Gallo, 2002). Scientific research has also fostered successful HIV prevention strategies such as male circumcision, condom use, and needle exchanges, which have averted millions of infections (Degenhardt et al., 2010; Madden & Wodak, 2014; Piot et al., 2015).

In addition to the scientific progress spawned by the virus, HIV has advanced human rights. Its disproportionate effect on the world's poorest and most marginalised groups inspired activism on an unprecedented scale. Across the globe, people refused to remain silent as their loved ones died (Killen, Harrington, & Fauci, 2012). They fought against stigma and discrimination and pressured their governments to fund research, prevention, and treatment (Brandt, 2013). Although HIV-related stigma and discrimination have diminished in some countries, they will remain present to some degree until HIV can be eradicated.

Before effective anti-retroviral medications were available, HIV progressed to AIDS, which was always fatal. HIV can be asymptomatic for a decade or more after infection. During this latent period, the virus can spread among sexual partners and drug-use networks long before illness appears. The protracted latent period of HIV infection facilitated its spread from remote central Africa to the rest of the world in just a few decades (Sharp &

Hahn, 2011). Identifying HIV infections by testing during this asymptomatic period is critical to individual health as well as the public's health. HIV treatment suppresses the virus, making it less likely to be transmitted to others.

This thesis explores HIV testing in a primary health care service in Perth, Western Australia, which is just one facet of the vast, multi-dimensional, and ever-evolving story of HIV. Australia is held in high regard across the globe for its success in averting a generalised epidemic through nonpartisan government initiatives such as needle syringe programs (Topp, Day, Iversen, Wand, & Maher, 2011). Other nations have and will continue to look to Australia as a world leader in effective HIV policies and interventions.

Background

Australia has a low HIV prevalence compared to other countries. Sustaining this low prevalence requires prompt identification and treatment of HIV infections. HIV incidence in Australia has been rising steadily since 1999, and in 2014, an estimated 26% of HIV-infected individuals had immune deficiency (defined as a CD4 count below 350 cells per microliter) at the time of diagnosis (The Kirby Institute, 2014). Australian data shows that the average interval between the time of HIV infection and diagnosis is 3.4 years, a significant period in which the virus could be transmitted to others (Australian Government Department of Health and Ageing, 2014). Case reports from around Australia indicate that HIV infections are often unrecognised by health care providers until AIDS-defining illnesses occur (Bell, Waddell, & Chynoweth, 2013; Darbar & Coyle, 2011; Ma, Smith, & Gordon, 2015). To decrease HIV transmission, the Australian Seventh National HIV Strategy recommends increasing HIV testing by 30% (Australian Government Department of Health and Ageing, 2014). The research project in this thesis explores a new approach to HIV testing that could help to achieve this goal.

Rationale for Opt-Out HIV Testing

The importance of HIV testing was highlighted when effective HIV medications (combined anti-retroviral treatment or cART) became available in 1996. These medications did not cure HIV, but they could suppress the virus to an undetectable level. HIV-infected people with access to cART experienced a reduction in viral load and normalisation of their immune function (Gulick et al., 1997; Hammer et al., 1996). People with HIV who thought they had a terminal illness now potentially had a full life ahead of them. Due to ongoing improvements in cART, lifespan in people with HIV continues to increase. A recent meta-analysis found that starting cART at age 20 added as much as 43.3 years to the lifespan (Teeraananchai, Kerr,

Amin, Ruxrungtham, & Law, 2016). Studies have shown that people who are aware of their HIV-positive status tended to adopt safer sexual and drug use practices, which is crucial for public health (Mattson et al., 2014). For individuals and the public to benefit from cART, HIV-infected people must be identified through testing and connected to health services.

Recent changes in cART recommendations make HIV testing even more urgent. Prior to 2014, only people with a certain level of immune deficiency (defined by CD4 count, a type of T-lymphocyte involved in immunity) were treated with cART. In the START trial, which began in 2009, HIV-infected patients were randomised to either immediate cART initiation or deferred cART initiation (to be commenced after the CD4 count dropped below 350 cells/cubic millimetres, which was usual practice at the time). The START trial was conducted across 35 countries and included 109 Australian patients. In 2015, the START trial was stopped when preliminary analysis showed that starting all HIV-infected people on cART reduced AIDS-related complications and deaths from AIDS (Lundgren et al., 2015).

In 2015, based on US Department of Health and Human Services guidelines (Panel DHHS 2016) and emerging data from START and other randomised controlled trials (Grinsztejn et al., 2014; Temprano, 2015), the Australasian Society for HIV Medicine recommended that all HIV-positive people start cART regardless of their CD4 count (Australasian Society for HIV Medicine, 2017). The Australian Government's Pharmaceutical Benefits Scheme had removed its CD4 count requirement for HIV-positive people to obtain cART in 2014, making effective HIV treatment available from the time of diagnosis (Australian Government Department of Health, 2016). With accessible and effective treatment available, it is imperative that people know their HIV status.

Transition to the Opt-Out Approach to HIV Testing

Throughout its history, the HIV epidemic has prompted innovations in clinical practice (e.g., the introduction of needle syringe programs and male circumcision) (Brandt, 2013). HIV testing processes are no exception. In the early years of the HIV/AIDS epidemic (1981-2006), HIV testing in the US required separate patient consent and pre-test counselling (Centers for Disease Control and Prevention, 1993). An HIV diagnosis was essentially a death sentence. Pre-test counselling was intended to prepare patients for the dire consequences that could result from a positive test: social stigma, employment discrimination, mental health problems, viral transmission from mothers to their babies, and ineligibility for health or life insurance (Weiss & Their, 1988). Pre-test counselling typically included education about the HIV infection and its usual course, how to minimise the risk of

being infected, and how the HIV test worked (important because early HIV tests were not as sensitive and took longer to process than current HIV tests) (Geren et al., 2014). It also provided an opportunity to assess patients' access to health care and other resources if they tested positive for HIV (Quinn, 1992).

No one in the international HIV community disputed the fact that it was in patients' and the public's best interest to identify HIV infections. But until the mid-2000s there was less agreement about the best strategy for HIV testing (Rhame & Maki, 1989). Because of the stigma and discrimination associated with HIV, mandatory testing of the general population had previously been discouraged on moral and ethical grounds (Judd, Biggs, & Burrows, 1989; O'Brien, 1989). As early as 1988, some doctors and scientists began to consider the individual and societal benefits of routine HIV testing in asymptomatic people (Rhame & Maki, 1989), although it would not become common practice for another 20 years.

By the mid-2000s, there was abundant evidence from some countries that risk-factor-based HIV testing was not identifying the extent of HIV infections (Goggin, Davidson, Cantril, O'Keefe, & Douglas, 2000; Lyons, Lindsell, Ledyard, Frame, & Trott, 2005; McDonald, Currie, & Bowden, 2006). Late diagnosis and deaths from AIDS were still problematic (Liddicoat et al., 2004). Pre-test counselling had not been shown to improve testing rates or health outcomes (Krauss et al., 2000; Robinson et al., 2002). In 2006, the US Centers for Disease Control recommended an opt-out approach to facilitate HIV testing for the general adult population (Branson et al., 2006). In opt-out testing, the HIV test is the default, meaning that patients are tested unless they explicitly refuse. Since the opt-out approach requires more patient effort to decline than to accept, HIV testing rates were expected to increase. (Opt-out testing should not be confused with mandatory testing; patients still test on a voluntary basis and provide informed consent). Subsequent research supported the hypothesis that opt-out testing was less time-intensive than risk factor assessment and pre-test counselling, and was associated with increased rates of testing (Metsch, Feaster, Gooden, & et al., 2013).

In opt-out HIV testing, pre-test counselling and risk factor assessment are omitted or deferred. For health care providers who were trained to do these steps before conducting an HIV test, this was a major change in practice that required them to accept new ideas about the importance and effectiveness of pre-test counselling. Now that cART had made HIV a manageable chronic disease, health care providers and patients were no longer faced with a test that essentially determined whether the patient would be likely to achieve a normal lifespan.

In Australia, HIV testing has not evolved in tandem with treatment. Pre-test counselling recommendations have not changed since the introduction of cART. For example, a pre-test counselling checklist from the Western Australia Department of Health recommends informing the patient what HIV is, how HIV is transmitted, that if a positive test occurs, how it is treated, how antibody tests work, and the need to re-test after three months (Government of Western Australia Department of Health, 2012). While this information is undoubtedly useful for patients, it also takes up precious time during the medical consult. There is no Australian evidence that pre-test counselling increases HIV testing rates or improves health outcomes. (Conversely, there is no Australian evidence that pre-test counselling decreases testing or worsens health outcomes). Studies from the US have shown that pre-test counselling does not decrease transmission of sexually transmitted infections. Pre-test counselling is costlier in terms of staff time and overhead than the more streamlined process of opt-out HIV testing (Metsch et al., 2013).

Pregnant women are the only people in Australia who are recommended to have opt-out HIV testing. This recommendation was put forward in a guideline by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists in 2006 (Royal Australian and New Zealand College of Obstetricians and Gynaecologists, 2015). A review of scholarly and grey literature for this thesis found no evidence that this recommendation was informed by a literature review, needs assessment or feasibility study. It was not supported by a formal implementation strategy or underlying theoretical framework. Further, there was no evidence of monitoring or evaluation of opt-out HIV testing in pregnant women after the recommendation was made. Although the lack of discussion about opt-out HIV testing for pregnant women may indicate that the practice may be feasible and acceptable to patients and health care providers in general, this cannot be assumed to be the case.

For non-pregnant individuals, HIV testing in Australia is guided by the National HIV Testing Policy, which was last updated in 2013 (Australasian Society for HIV Medicine, 2014). The Australasian Society for HIV Medicine states that "a sexual, drug use and medical history should be conducted to assist in determining whether an HIV test should be conducted". Indications for HIV testing include clinical signs (such as an AIDS-defining illness or commonly co-occurring infections like tuberculosis), risk behaviours (specifically injecting drug use or unprotected sexual intercourse), health care worker exposure, and patient request for testing. Whilst these guidelines are useful in relation to the decision to test for HIV or not, there is international evidence that risk factor-based testing is not effective in identifying some HIV infections. Opt-out HIV testing would not detract from the need to test

in obvious situations such as an AIDS-defining illness or health worker exposure, but it would abbreviate the pre-test counselling, history-taking and risk factor assessment process advocated by current Australian recommendations. Eliminating or truncating these established practices would represent a paradigm shift for Australian health care providers. This research project aimed to explore the acceptability and feasibility of this shift in a general practice in Western Australia.

Research Objectives

Objective 1: To describe health care providers' perceived barriers, facilitators, beliefs, attitudes and self-efficacy in relation to opt-out HIV testing.

Objective 2: To construct a health care providers' health belief typology relating to HIV risk and testing in their client population.

Objective 3: To explore evidence of acceptability by health care providers related to an opt-out HIV testing strategy, to inform a possible change in Australian practice.

Objective 4: To design and trial an opt-out model of HIV testing in a primary health care setting, and examine health care providers' perceptions of the change in practice.

Objective 5: To determine if the pilot test increased HIV testing rates.

Objective 6: To evaluate the acceptability and feasibility of opt-out HIV testing for health care providers.

These objectives evolved over the course of the research project. Initially, the second objective was to construct a typology of health care providers' beliefs about opt-out HIV testing. As the research progressed, the literature review expanded to include other theories and concepts. Peer reviewers for the third publication (about Australian health care providers' views on opt-out HIV testing) suggested an exploration of theories beyond the Health Belief Model. Whilst health care providers' beliefs were important, they did not address the behavioural and operational aspects of opt-out HIV testing. It became clear that the opt-out HIV testing project in this thesis required a broader framework that explored the basis for and implications of, default-based interventions (Behavioural Economics [Rice, 2013]) and operational implementation of the approach (Normalisation Process Theory [May et al., 2011]).

Conceptual Framework for the Thesis

The overarching conceptual framework for this thesis was implementation science, also known as knowledge translation or translational medicine. Implementation science

examines the process of transforming research evidence into clinical practice (Braithwaite, Marks, & Taylor, 2014). With this approach, diverse theories (such as Diffusion of Innovations or Normalisation Process Theory) and methodologies (with an emphasis on mixed-methods) are used to understand the gaps and bridges between science and clinical practice (Peters, Tran, & Adam, 2013).

A common premise in implementation science is that health care providers and policy makers are reluctant to change clinical practice or policy according to scientific evidence (Greenhalgh & Wieringa, 2011). The research objectives in this thesis did not presume that health care providers are inherently reluctant to adopt new practices. Full awareness and integration of evidence are rarely achieved due to the complexity and decision-making burden of day-to-day clinical practice. For example, health care providers may intend to follow a guideline, but because they see their patients as individuals with unique needs to whom the guideline may not fully apply, they continue their usual (non-evidence based) practice (Greenhalgh & Wieringa, 2011). This research was designed to explore how health care providers' beliefs and attitudes influence how they operationalise a change in practice.

Implementation science can also inform the process of eradicating or doing away with practices that are not supported by evidence. This thesis was developed around the idea that clinical practices (such as pre-test counselling) that do not lead to improved health outcomes or efficiency should be discontinued. The final phase of the study explored health care providers' views on HIV testing without pre-test counselling.

One of the tenets of implementation science is that practice changes should not just happen without following a well-designed blueprint to guide implementation. Effective translation of evidence to clinical practice requires involvement in: needs assessment, planning, feasibility or pilot studies, and ongoing evaluation (Hargreaves et al., 2016; van Bon-Martens, van de Goor, & van Oers, 2016). From the start, this research set out to explore and develop an opt-out HIV testing intervention informed by a needs assessment, literature review, theoretical framework and implementation plan.

Study Design

This thesis is the culmination of a research project that aimed to explore opt-out HIV testing in Western Australia. Although there was abundant research about opt-out HIV testing in other countries (Haukoos et al., 2011; O'Kelly, Byrne, Naughten, Bergin, & Williams, 2016; Yazdanpanah et al., 2010; Yazdanpanah et al., 2013), an initial scoping review of the scholarly and grey literature testing found limited research to inform opt-out

HIV testing projects in Australian health care settings.

On this basis, an exploratory design was developed for this study. Exploratory research is the initial step in a broader research project about an unknown or loosely-defined subject (Stebbins, 2001). Unlike descriptive research, which simply counts, defines or measures objective phenomena, exploratory research generates themes that build theory or develop other research questions. Exploratory research is often qualitative because there is insufficient knowledge of the phenomenon from which to design quantitative surveys or experiments. When presented on its own, exploratory research cannot make inferences or generalisations and never draws final conclusions. Instead, exploration of themes identifies potential associations between phenomena that can lead to further refinement of theories and hypotheses. Exploratory research can also be used to identify outcomes (duToit, 2015). In this thesis, exploratory research was used to explore particular outcomes (feasibility, acceptability and testing rates) of opt-out HIV testing on a small scale, laying the foundation for implementation into a larger population or a different setting.

This exploratory research project is presented as a thesis by publication (Figure 1). The thesis began with integrative and systematic reviews of the literature on opt-out HIV testing to evaluate existing research on the topic in both international and Australian contexts (Chapter 2). These reviews led to an initial exploration of Australian health care providers' views on opt-out HIV testing through qualitative interviews. The participants' beliefs and attitudes about opt-out HIV testing were first analysed according to the Health Belief Model. As mentioned previously, subsequent in-depth analysis led to the conclusion that the Health Belief Model alone did not account for the breadth of themes about opt-out HIV testing that had emerged from the data (Chapter 3). A comprehensive theoretical framework for implementation of opt-out HIV testing was then developed (Chapter 4). This preliminary work formed the foundation for a trial of opt-out HIV testing in a general practice, which is the final study in this thesis (Chapter 5).

In this final study, opt-out HIV testing was conducted by the health care providers at a general practice for a one-year period and compared to usual practice (in terms of the number of tests conducted in the previous year). At the end of the intervention, the health care providers were interviewed about their experiences with opt-out HIV testing. Research has shown that people describe their experiences through the prism of their beliefs and biases; qualitative findings alone do not describe an objective reality (Paley & Lilford, 2011). In other words, it was important to compare the participants' thoughts about opt-out HIV testing with the amount of testing they actually performed. Quantitative data were collected to

describe an objective outcome (number of HIV tests with usual practice compared to the number of HIV tests with opt-out testing).

The outcomes of the exploratory research were 1) an original implementation guide for opt-out HIV testing based on a tested theoretical framework; 2) an initial understanding of Australian health care providers' views on opt-out HIV testing; and 3) a preliminary analysis of the feasibility and acceptability of opt-out HIV testing in a general practice. Findings presented in this thesis provide evidence that can underpin future research and policy development.

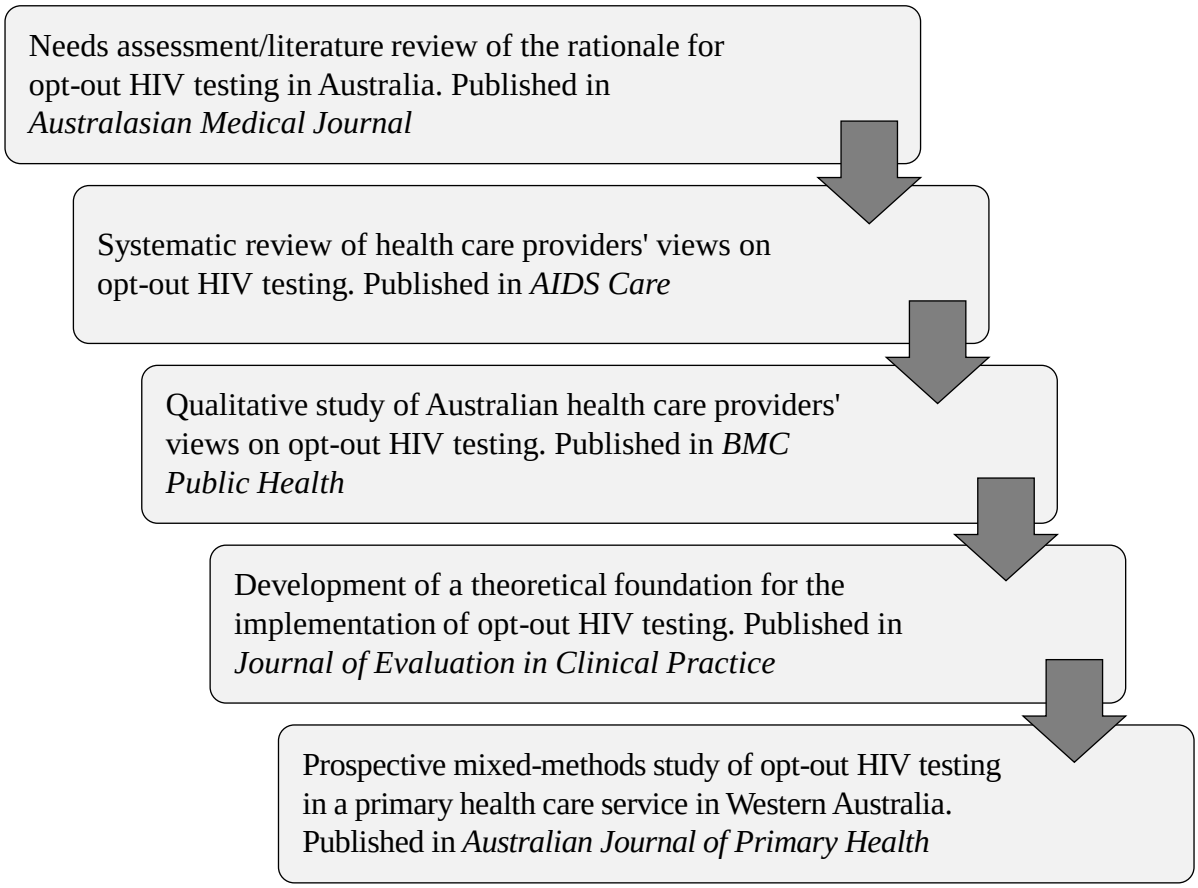

Figure 1. PhD by Publication

CHAPTER 2

LITERATURE REVIEWS

This chapter is comprised of two published literature reviews and a synopsis of the existing state of knowledge relating to opt-out HIV testing. The first publication, Leidel, S., McConigley, R., Boldy, D., Girdler, S., & Wilson, S. (2015). Should Australia consider opt-out HIV testing? *Australasian Medical Journal 8*(1), 30-32. http://dx.doi.org/10.4066/AMJ.2015.2290, was essentially a needs assessment and discussion of the potential benefits of the approach. Based on a scoping review of the international literature about opt-out HIV testing (current through the time of article submission, December 2014) the article provided a background for the present research. Australian HIV data was presented, showing trends (such as an increasing rate of new HIV diagnoses among heterosexuals), supporting an exploration of opt-out HIV testing in Australia.

The next section of this chapter is a second publication, Leidel, S., Wilson, S., McConigley, R., Boldy, D., & Girdler, S. (2015); and Health-care providers' experiences with opt-out HIV testing: a systematic review. *AIDS Care, 27*(12), 1455-1467. *http://dx.doi.org/10.1080/09540121.2015.1058895*. This article synthesised findings from a systematic review of health care providers' views on opt-out HIV testing. The studies meeting inclusion criteria were based on research from outside Australia, indicating there was a gap in knowledge about opt-out HIV testing in Australia.

Following this publication, an additional literature review was undertaken of other studies about health care providers' experiences with opt-out HIV testing (including Australian studies). Because of the large number of articles on opt-out HIV testing published since "Should Australia consider opt-out HIV testing" and "Health care providers' views on opt-out HIV testing" were published (January and July 2015, respectively), the additional review includes current articles through August 2016. This final section expands on the published articles with an updated comprehensive analysis of key concepts of opt-out HIV testing (including consent, stigma, pre-test counselling, linkage to care, ethical challenges, cost, and efficiency). Finally, gaps in knowledge about opt-out HIV testing in Australia that led to this research project are reviewed.

Article 1. Should Australia consider opt-out HIV testing

AMJ Australasian Medical Journal [AMJ 2015;8(1):30–32]

Should Australia consider opt-out HIV testing?

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EDITORIAL

Please cite this paper as: Leidel S, McConigley R, Boldy D, Girdler S, Wilson S. Should Australia consider opt-out HIV testing? AMJ 2015;8(1):30–32. http://dx.doi.org/10.4066/AMJ.2015.2290

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In 2012 and 2013, Australia had the highest incidence of HIV diagnoses in 20 years.[1] While there is no imminent threat of a generalised epidemic in Australia, the recent increase in HIV diagnoses reflects changing infection patterns that warrant an exploration of current testing practices. Opt-out HIV testing could decrease the number of undiagnosed infections and provide for timely connection to care.

Opt-out testing is a method for detecting disease in which patients are informed that they will be tested for the disease unless they decline. In opt-out HIV testing, patients in the general population between the ages of 13 and 64 years are tested for HIV at least once in their lifetime in a routine health encounter, such as at a GP consultation or emergency department visit.[2] Separate written consent and HIV prevention counselling would not be compulsory. Opt-out testing is done without a formal HIV risk assessment (such as number of sexual partners, history of sexually transmitted infections (STIs), or injecting drug use).[2] It may be a part of, or separate from, STI testing. High-risk groups such as men who have sex with men (MSM) or injecting drug users (IDU) would test more frequently as per current guidelines, and pregnant women would continue to be tested on a routine basis.

Decreasing the number of undiagnosed HIV infections is one of the objectives of Australia's Seventh National HIV Strategy.[3] According to national surveillance data, up to 25 per cent of HIV infections in Australia remain undiagnosed.[1] HIV-positive individuals who are unaware of their status often have an elevated viral load, and are consequently more infectious than HIV-positive individuals who are virologically supressed with medication. Undiagnosed people transmit up to 31 per cent of new HIV infections.[1] Morbidity and mortality decrease markedly if patients are linked to HIV treatment early in the course of their infection. Opt-out testing would increase the number of individuals tested for HIV, which could reduce the number of undiagnosed infections and prevent future transmissions.

Research suggests that people are less likely to test for stigmatised diseases like HIV, because it could imply that they have engaged in atypical or even immoral behaviour.[4] Opt-out testing does not target individuals or their behaviours, making it similar to testing for non-stigmatised diseases such as diabetes. A normalised, morally neutral approach could increase HIV testing rates, reducing late diagnosis.

Late HIV diagnosis (defined as a CD_4 count of less than 350 at diagnosis) remains a significant challenge in Australia, comprising 29.6 per cent of new diagnoses in 2013.[1] Between 2008 and 2012, 50 per cent of heterosexually-transmitted HIV infections were diagnosed late, probably as a result of less frequent testing among heterosexuals.[1] French and American studies have shown opt-out HIV testing in the general population reduces the time between infection with the virus and diagnosis. Further, the CD_4 count at diagnosis is higher.[2,5] Though Australian HIV patterns and prevalence are different from France and the United States (US), it is plausible that adopting opt-out testing in Australian health settings (such as general practice or emergency departments) could potentiate earlier diagnosis and connection to care.

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Opt-out HIV testing could pick up infections in people who do not present for testing or who do not consider themselves to be at risk. It would be particularly beneficial for heterosexuals. While HIV transmission in Australia is most common among high-risk groups such as MSM and IDU, heterosexual transmission of HIV has increased by 29 per cent between 2003 and 2012, from 203 new infections in 2003 to 313 in 2013.[1]

Testing that occurs outside of dedicated HIV testing centres can capture a broader section of the population, including those who test infrequently or perceive themselves as low risk. A range of testing settings is necessary because even sexual health services do not identify all HIV infections. A study conducted in Canberra in 2006 found that 58 per cent of HIV-infected people had attended a sexual health clinic prior to the consultation that led to their diagnosis. In the same study, 95 per cent of patients had presented with risk factors that warranted HIV testing, but testing did not occur until later.[6]

Societal factors such as Australia's resource boom have resulted in increased mobility and disposable income. It is not unusual for Australians to live for extended periods in countries with higher HIV prevalence. There has been an increase in heterosexual HIV transmission among male fly-in, fly-out workers from Western Australia and Northern Territory who travel frequently to Thailand and Indonesia.[1] Cultural and social factors identified by Brown[7] make it unlikely that this group would self-select for HIV testing. Any infections in this group could be identified earlier by conducting opt-out HIV testing in places where they are most likely to seek general medical care (such as occupational health, general practice, or emergency departments).

Cost-effectiveness modelling would be required before opt-out HIV testing could be implemented throughout Australia. Cost effectiveness varies with disease prevalence, which for HIV is presently 0.15 per cent among Australians over age 15.[1] Research from the US has shown that opt-out testing is cost effective even at 0.05 per cent prevalence.[8] A French study found that one-time, routine HIV testing in the general population was similar in cost effectiveness to other screening programs such as annual chlamydia testing in young adults.[5] These findings may not be generalisable to Australia because of differences in health systems and disease patterns, but modelling showed that opt-out testing among Australian pregnant women is cost effective at prevalence rates greater than 0.004 per cent.[9]

As with any diagnostic investigation, an opt-out HIV testing program must ensure compliance with state and national laws, informed consent, and patient confidentiality procedures. Health providers should perform and document thorough pre- and post-test counselling and facilitate immediate referrals to HIV treatment centres in case of positive results. Since opt-out HIV testing is performed without clinical suspicion or risk factor assessment, HIV diagnoses with this approach (though infrequent) would likely be unanticipated.[13] Consequently, opt-out testing protocols must mitigate the potential effects of diagnostic labelling (such as stigmatisation) and address the mental health consequences of the testing or results (such as self-harm or harm to an individual believed to have transmitted the infection).[10,11,13] Psychosocial support for newly diagnosed individuals is essential for self-management and engagement with treatment.[12] An opt-out testing program should use HIV tests with a high specificity to minimise false positives, which are more common in populations with lower disease prevalence.

In opt-out HIV testing, the onus is on the patient to decline the test. Research from the US and UK has shown that most patients are willing to be tested.[14] However, it is essential that there is no coercion or negative consequence for patients who do not wish to test.[10–13]

Opt-out testing in the US was facilitated by Centers for Disease Control funding for dedicated staff to perform testing and counselling. Australia may have other priorities for scarce healthcare resources. We are conducting a two-phase feasibility study of opt-out HIV testing in GP practices. Preliminary findings suggest that healthcare providers see public health benefits to opt-out HIV testing, but are concerned about the increased workload and potential for pre-test counselling to be overlooked.

The Seventh National HIV Strategy aims to sustain Australia's low prevalence of HIV, but its emphasis on targeted, risk factor-based testing should be reconsidered. International and preliminary Australian evidence indicates that opt-out HIV testing is acceptable and cost effective. Given the recent increase in HIV diagnoses in Australia, this is an opportune time to explore the feasibility of opt-out HIV testing to improve early diagnosis and connection to care in non-traditional populations.

AMJ Australasian Medical Journal [AMJ 2015;8(1):30–32]

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PEER REVIEW

Peer reviewed.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

Article 2. Health care providers' experiences with opt-out HIV testing: a systematic review

AIDS Care: Psychological and Socio-medical Aspects of AIDS/HIV
Publication details, including instructions for authors and subscription information:
http://www.tandfonline.com/loi/caic20

Health-care providers' experiences with opt-out HIV testing: a systematic review

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Published online: 14 Aug 2015.

AIDS Care, 2015
http://dx.doi.org/10.1080/09540121.2015.1058895

Health-care providers' experiences with opt-out HIV testing: a systematic review

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(*Received 23 January 2015; accepted 2 June 2015*)

HIV is now a manageable chronic disease with a good prognosis, but early detection and referral for treatment are vital. In opt-out HIV testing, patients are informed that they will be tested unless they decline. This qualitative systematic review explored the experiences, attitudes, barriers, and facilitators of opt-out HIV testing from a health-care provider (HCP) perspective. Four articles were included in the synthesis and reported on findings from approximately 70 participants, representing diverse geographical regions and a range of human development status and HIV prevalence. Two synthesized findings emerged: *HCP attitudes* and *systems*. The first synthesized finding encompassed HCP decision-making attitudes about who and when to test for HIV. It also included the assumptions the HCPs made about patient consequences. The second synthesized finding related to systems. System-related barriers to opt-out HIV testing included lack of time, resources, and adequate training. System-related facilitators included integration into standard practice, support of the medical setting, and electronic reminders. A common attitude among HCPs was the outdated notion that HIV is a terrible disease that equates to certain death. Some HCPs stated that offering the HIV test implied that the patient had engaged in immoral behaviour, which could lead to stigma or disengagement with health services. This paternalism diminished patient autonomy, because patients who were excluded from opt-out HIV testing could have benefited from it. One study highlighted the positive aspects of opt-out HIV testing, in which participants underscored the professional satisfaction that arose from making an HIV diagnosis, particularly when marginalized patients could be connected to treatment and social services. Recommendations for opt-out HIV testing should be disseminated to HCPs in a broad range of settings. Implementation of system-related factors such as electronic reminders and care coordination procedures should be considered, and a social-justice commitment among HCPs should be encouraged.

Keywords: HIV; opt-out testing; qualitative synthesis; systematic review; health-care provider

Introduction

HIV is now a manageable chronic disease with a good prognosis, but early detection and referral for treatment are vital (Nakagawa et al., 2012; van Sighem, Gras, Reiss, Brinkman, & de Wolf, 2010). Health-care providers (HCPs) commonly perform HIV testing based on patient risk factors, clinical indicators, or by patient request (Bayer & Fairchild, 2006; Gostin, 2006). Research has shown that HIV testing without risk factor assessment may detect the virus earlier and improve survival (April, Chiosi, Paltiel, Sax, & Walensky, 2011). In opt-out HIV testing, patients are informed that they will be tested unless they decline (Branson et al., 2006). This method aims to decrease the number of undiagnosed HIV infections and ensure timely connection to treatment (Brown, Nardone, & Delpech, 2014; Long et al., 2014). Early initiation of anti-retroviral medications has been shown to improve morbidity and reduce mortality (Grinsztejn et al., 2014; Okulicz et al., 2014).

In 2006, the United States Centers for Disease Control (CDC) recommended opt-out HIV testing for individuals between the ages of 13 and 65 years at least once in their lifetime (in areas with an HIV prevalence of 0.1% or greater) (Branson et al., 2006). Since then, a range of influential groups has recommended opt-out HIV testing in health-care settings (American Academy of Pediatrics Committee on Pediatric AIDS, 2011; British HIV Association, 2008; Moyer & U.S. Preventive Services Task Force, 2013; UNAIDS-World Health Organization, 2004; World Health Organization, 2012). HCPs now conduct opt-out HIV testing in a variety of contexts, both geographical and clinical, and in settings that ranged from very low to very high prevalence (Haukoos et al., 2010; Kayigamba et al., 2014; Loos, Manirankunda, Hendrickx, Remmen, & Nöstlinger, 2014; Nardone, Delpech, Gill, Fenton, & Anderson, 2013; Thornhill, Mandersloot, Bath, & Orkin, 2014). From an international perspective, it is not known to what extent HCPs find opt-out HIV testing acceptable or feasible, and if it differs according to clinical setting, geographical location, or prevalence. For opt-out HIV testing to achieve its goals, HCP experiences and perceptions of

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this approach should be explored systematically. This review explored the experiences, attitudes, barriers, and facilitators of opt-out HIV testing from a HCP perspective.

The aim of this study was to systematically review qualitative studies of HCP experiences with opt-out HIV testing. We chose the qualitative paradigm to explore diverse narratives of HCPs' experiences that could not be measured empirically (Jensen & Allen, 1996; Ma, 2000; Sandelowski, Docherty, & Emden, 1997). These narratives will be useful for designing and implementing opt-out HIV testing programs in a broad variety of health-care settings (April et al., 2011; O'Byrne, 2012).

Method

Study identification

In March 2014, we searched the following databases: CINAHL, EMBASE, Medline, ProQuest, Scopus, Science Direct, and Web of Science. Due to the paucity of articles about opt-out HIV testing prior to 2004, we limited the dates to 2004 through March 2014. The search terms were based on HCP roles and their synonyms, such as health personnel, nurses, and doctors. Search terms for opt-out testing included routine, provider-initiated, universal, and non-targeted. We excluded articles that indicated opt-in or other types of testing, such as targeted, risk factor-based, and home-based testing. Only papers published in English were included (see Figure 1).

Quality assessment

Two researchers independently assessed the retrieved articles against the eligibility criteria (Watts, 2000), then assessed the remaining articles for methodological quality using the Standard Quality Assessment Criteria for Evaluating Primary Research Papers (Kmet, Lee, & Cook, 2004) see appendix 1. We retained articles when we reached consensus of the quality scores, and resolved differences through discussion. We then extracted data using the Joanna Briggs Institute Data Extraction Tool for qualitative studies (Joanna Briggs Institute, 2014) see appendix 2. Two researchers independently extracted original subthemes from the studies and assessed their credibility using Joanna Briggs Institute criteria (Joanna Briggs Institute, 2014).

Results

Profile of studies represented in review

Four articles were included in the final synthesis and reported on findings from approximately 70 participants – with one study not providing the exact number of participants (Horwood, Voce, Vermaak, Rollins, & Qazi, 2010) (see Table 1).

One study investigated perceptions of doctors-in-training (Brennan et al., 2013), two examined nurses (Evans & Ndirangu, 2011; Horwood et al., 2010), and the remaining article engaged an inter-professional sample that included doctors, nurses, and "key informants" – identified as performing non-clinical duties (Christopoulos et al., 2011).

The participants from these studies were recruited from diverse geographical regions, representing a range of human development status as defined by the United Nations Human Development Index (UNHDI), with marked variation in HIV prevalence (United Nations Development Programme, 2014). Two studies were from dissimilar settings in the United States (a primary care clinic and an emergency department [ED]) with HIV prevalence of 0.4% and 3.0%, respectively (Brennan et al., 2013; Horwood et al., 2010). The study conducted in South Africa (whose UNHDI is medium) had the highest HIV prevalence at 29.1% (Horwood et al., 2010). The fourth study was conducted in Kenya, which has a lower HIV prevalence than South Africa at 7.1%, but is at a lower development stage according to UNHDI (Evans & Ndirangu, 2011).

Two synthesized findings emerged: *HCP attitudes* and *systems* (see Table 2). The first synthesized finding encompassed HCP decision-making attitudes about who and when to test for HIV. It also included the assumptions the HCPs made about patient consequences. The second synthesized finding was *systems*. This included system-related barriers to opt-out HIV testing, such as lack of time, resources, and adequate training. This synthesized finding also contained factors that enabled opt-out HIV testing, such as integration into standard practice, support of the medical setting, and electronic reminders.

Theme 1: health-care provider attitudes

Across the included studies, HCPs held strong beliefs about who should be tested for HIV. These beliefs were commonly underpinned by moral or values-based judgments. One participant expressed surprise that a married person would agree to have an HIV test, perhaps based on an assumption that married people do not engage in high-risk behaviours (Brennan et al., 2013). Another HCP stated that nurses in the ED assumed that a "little old lady" did not need to be tested for HIV (Christopoulos et al., 2011, p. 3). In another instance, an HCP said that it was "easy" for HIV-positive pregnant women,

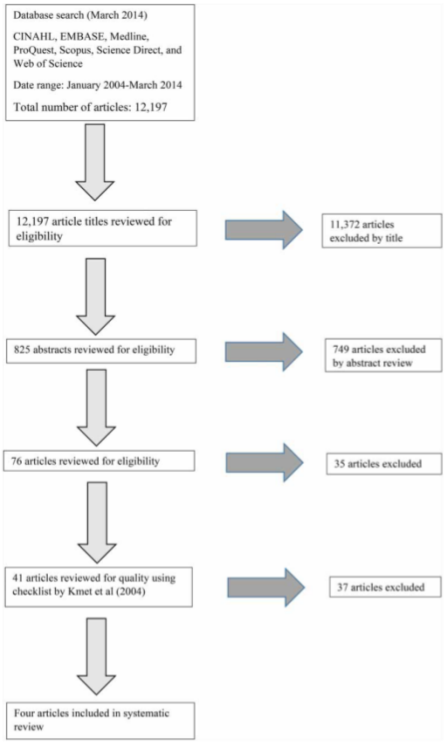

Figure 1. Database search.

because despite the fact that they had "done this thing" [unprotected sexual intercourse], health interventions could prevent transmission of the virus to their babies (Horwood et al., 2010, p. 316).

A proportion of HCP participants in all studies mentioned discomfort with disclosing HIV-positive results. In one case, the participant was more comfortable with conveying news of a child's accidental death than with giving a positive HIV result (Christopoulos et al., 2011). This participant recognized the contradiction inherent in this situation, since "we give bad news all the time in the ED," indicating that HCPs consider a positive HIV diagnosis to be a remarkable event, even in a setting in which negative outcomes are common (Christopoulos et al., 2011, p. 6).

Several participants stated that opt-out HIV testing could result in stigmatization or coercion. One nurse stated that offering testing implied that she was "suspecting" a child of having HIV – and that this suspicion would put her at risk of legal action by the child's parents (Horwood et al., 2010, p. 316). One participant even equated provider-initiated HIV testing with "provider coercion," suggesting that with the opt-out approach, patients were not truly free to decline the test (Evans & Ndirangu, 2011, p. 1294). Another HCP stated that in the local culture, mentioning an HIV test (or simply performing a physical assessment for lymphadenopathy, a sign of HIV) would foster patient stigmatization – even if the person tested negative (Horwood et al., 2010). It was not clear if these concerns were real or perceived outcomes of the opt-out approach to HIV testing.

Some participants expressed concern that opt-out HIV testing would conflict with their patients' health priorities or cause them to disengage with care. One ED participant asserted that HIV testing should be viewed in the context of the patient's priorities: Though there may be a benefit to early HIV diagnosis, patients expect their presenting complaint (i.e. acute illness or injury) to be the top priority during the encounter (Christopoulos et al., 2011). Participants also predicted that if HCPs offered the HIV test (without waiting for patients to request it), patients would be less likely to return to the clinic (Horwood et al., 2010).

Insufficient pre-test counselling was an area of concern for several participants. Some HCPs anticipated negative consequences from reduced pre-test counselling, asserting that without a preliminary discussion of the consequences of being HIV positive, patients would be unable to cope with a positive HIV diagnosis (Evans & Ndirangu, 2011; Horwood et al., 2010). One nurse expressed dismay that doctors were testing patients without formal pre-test counselling, implying that she needed to protect patients from the supposed harm of HIV testing (Evans & Ndirangu, 2011).

Despite these attitudinal barriers, some HCPs were upbeat about the value of opt-out HIV testing. In the study from an American ED, HCPs described the unique benefits of opt-out testing for marginalized patients who had no other access to primary care. Their comments suggested that HCPs saw early HIV diagnosis and linkage to care as an affirming aspect of their practice. One participant from this study was able to re-engage an HIV-positive patient into receiving care as a result of the HIV testing program, which was described as an unanticipated, but encouraging, outcome of the opt-out approach (Christopoulos et al., 2011).

Theme 2: systems

Participants identified system-related barriers to opt-out HIV testing, such as lack of time and resources, a need for more training, and competing priorities

Table 1. Summary of reviewed articles.

Author and year	Country	Population (*n*)	Study design and method	Phenomena of interest	Analysis	Main themes	Quality appraisal
Brennan et al. (2013)	United States	Focus groups of internal medicine residents in primary care and veterans' health	Qualitative	Knowledge, attitudes and behaviors of internal medicine residents	Thematic analysis	1. Integration into standard practice 2. Resident perceptions of patients' attitudes 3. Strategies for opening the discussion with patients 4. Use of electronic medical record cues	18/20
Christopoulos et al. (2011)	United States	In-depth interviews with key informants involved in development and implementation of testing programs ($n = 15$)	Qualitative evaluation	Factors shaping the adoption and evolution of specific program elements; barriers and facilitators to testing	Framework analysis	1. ED HIV testing models 2. Factors shaping the adoption and evolution of different testing models 3. Concern about disclosing a positive HIV result 4. Serving vulnerable urban populations 5. The secondary gain of re-engaging known HIV-infected patients in care 6. The support of the medical setting	17/20
Evans and Ndirangu (2011)	Kenya	25 nurses (focus group = 12; interviews = 13) from 11 different health facilities; 13 worked in inpatient settings and 12 worked in outpatient settings and/or held managerial positions	Qualitative, multi-method design Interpretative, qualitative methodology 2× focus groups 713 in-depth individual interviews	(i) To investigate key challenges in PITC (provider-initiated testing and counselling) from a nursing perspective and (ii) To explore ways in which the principle of the 3Cs (consent, confidentiality and counselling) was being managed in everyday practice	Inductive, thematic content analysis (Boyatzis, 1998)	1. The contradictions of routinization 2. Everyday ethics 3. Workplace environment and support	15/20

Horwood et al. (2010)	Kwa-Zulu Natal and Limpopo provinces, South Africa	Total of IMCI-trained nurses (integrated management of childhood illness) not given but up to 10 identified in each area	Qualitative; focus group discussions	The attitudes towards, and experiences of, implementation of routine checks for HIV in the context of IMCI implementation, from the perspective of both caregivers and nurses	Manual content analysis	Health worker perspectives and barriers to implementation: 1. Attitudes of health workers 2. Recording of clinical findings on the patient record card 3. Inadequate training 4. Time consuming 5. Mothers may need permission from other family members for HIV testing of the child 6. Children come with multiple carers 7. Enabling factors for implementation	16/20

(Evans & Ndirangu, 2011). Some participants indicated that pre-test counselling training for HCPs should be a requirement for performing HIV testing – though this would not be consistent with the intent of the opt-out approach (Evans & Ndirangu, 2011; Horwood et al., 2010). Brennan et al. (2013) found that in the primary care context, HCPs often had more important health priorities than HIV testing, such as cholesterol screening. In low-resource settings, HCPs were concerned about the additional burden that increased HIV testing could cause for patients who could barely meet their basic needs, let alone manage HIV infection (Evans & Ndirangu, 2011).

Although some health system factors hindered opt-out HIV testing, other factors supported this approach. Normalizing HIV testing within HCP-patient conversations was beneficial. For example, some HCPs found that describing HIV as a chronic, manageable disease (comparable to diabetes) was an effective way to increase testing rates (Brennan et al., 2013). This is consistent with previous research on normalization of HIV (Goetz et al., 2008, 2009). Routinely incorporating opt-out HIV testing into the HCPs' daily clinical tasks (such as taking blood pressure) made it more likely to occur (Brennan et al., 2013).

Some participants identified that well-resourced clinical environments facilitated opt-out HIV testing. For example, across three distinct models of ED-based HIV testing, HCPs were in favor of the opt-out approach because in this resource-rich environment, care coordination could begin immediately after an HIV-positive diagnosis, avoiding potential loss of patient follow-up (Christopoulos et al., 2011). Participants were also motivated by the benefit of having more patients' HIV status documented in the medical record, which enabled them to provide individualized care at every visit (Christopoulos et al., 2011). Similarly, electronic medical record reminders kept HIV testing on the HCPs' agenda during patient encounters when there were multiple health issues to address (Brennan et al., 2013).

Discussion

Although there were limited studies eligible for this systematic review, it provided valuable information about the benefits of and impediments to opt-out HIV testing from a HCP point of view. It also highlighted a discrepancy between the current HIV testing recommendations and actual practice across disparate health-care settings. HCP attitudes about who should be tested were value-laden and not

Table 2. Synthesized themes and illustrative quotes.

Synthesized themes and original subthemes	Credibility Score	Illustrative quotes
Attitudes of HCPs Evans and Ndirangu (2011) • Everyday ethics: the challenge of dealing with ethically complex client situations in which the principles of the 3Cs could be difficult to uphold	Unequivocal	" … you find you might be aggressive for the sake of helping them, not because you want to create harm, but just because you want them to benefit, even though you have to use a cold and aggressive way of handling such a situation … Like there was a girl on the ward and I told her – either you lose your life or comply with the protocols of the hospital … then, you see … it was like forcing … but at the end of it she accepted. But it was for her benefit." Evans and Ndirangu (p. 1294) "It happens many times when the doctors are doing their rounds. Many are the times when they don't inform the patient what is wrong with them. The doctor notes down the test and the next thing you know, the clinical officer is poking into this patient drawing blood and the patient doesn't know why. The patients are so innocent, they trust that whatever you are doing is for his own good … they do not demand to know." Evans and Ndirangu (p. 1294) "We talk as if it's a bad thing; we also discuss these patients despite saying that we are going to keep the confidentiality – so of course patients will not want to test." Evans and Ndirangu (p. 1294). "If we coerce these patients to be tested – then they won't come back. It won't be provider-initiated, it will be provider coercion." Evans and Ndirangu (p. 1294) "You test them and then they tell you their history and you just don't know what to do next. They are poor and they can't afford food, and then you ask yourself, 'what can I do to help this person?' It really affects me." Evans and Ndirangu (p. 1295)
Attitudes of HCPs Christopoulos et al. (2011) • Concern about disclosing a positive HIV result • Serving vulnerable populations • The secondary gain of re-engaging HIV-positive patients in care	Unequivocal	"I can't tell somebody they have HIV. That's too devastating … Yeah, I don't have a problem telling a family that their six-year-old was killed in a car accident. I can do that. But I can't tell someone they have HIV." Christopoulos et al. (p. 6) "We're convinced that one of the reasons that the clinicians say we can't disclose a positive HIV test result in the emergency department really comes from stigma. Because they disclose bad news all the time in emergency departments." Christopoulos et al. (p. 6)
Attitudes of HCPs Horwood et al. (2010) • Attitudes of health workers	Credible	"You have to ask every mother that comes about [HIV] status … but it is so embarrassing, because after they go outside [they say] "I will never come back to this clinic: that nurse in that consulting room asked about HIV." Horwood (p. 315) "No, I don't feel that we have to routinely do all children, because some of them they are healthy and good, and even if you assess the road to health chart they don't come as a regular client. Some they just come when there is an outbreak of flu." Horwood et al. (p. 316) "They [nurses] tell the [pregnant] women they have indulged themselves in unprotected sex and now it is easy for them because the government has put this PMTCT [prevention of mother to child transmission] program in action. So they must test [for HIV] because they have done this thing." Horwood et al. (p. 316)
Attitudes of HCPs Brennan et al. (2013) • Resident [doctors] perceptions of patient attitudes	Credible	"I have been surprised by the number of people (patients) who are married and very willing to get HIV tested. I always feel like I am saying something about them or their spouses, but I haven't found that." Brennan et al. (p. 202)

(*Continued*)

Table 2. Continued.

Synthesized themes and original subthemes	Credibility Score	Illustrative quotes
Systems Brennan et al. (2013) • Integration into standard practice • Electronic medical record cues • Strategies for opening the discussion: Normalizing screening and referring to expert authorities	Credible	"It's lower on my priority list for, say, a healthy 55-year-old man. I go through all their preventive issues, but if they come in with 6 chief complaints for a 1-hour physical, that's one of the things I may not get to along with a living will or health care power of attorney. Those are lower on my preventive screening list, as opposed to cholesterol or colonoscopies. I would say about 25% of the time I don't get to it." Brennan et al. (p. 201) "I have a section on health maintenance [in the EMR] for all my patients. I document when I asked last, what their response was, and if they'd ever been screened before. So I tend to bring it up [with my patients]." Brennan et al. (p. 203) "Everybody in my clinic seems to have diabetes, so they know what an A1C is … I have one patient who just understands it that way—like any other chronic condition, you just have to screen for it." Brennan (p. 202)
Systems Evans and Ndirangu (2011) • The contradictions of normalizing a highly stigmatized disease and the difficulty in providing client-centered care within a routinized and target-oriented work culture • Lack of time, resources, space and recognition within workplace environments		"Pre-test counselling is the most important thing because it prepares the patient to receive a positive result—if you just test—where do you start when the patient turns out to be positive?" Evans and Ndirangu (p. 1294)
Systems Christopoulos et al. (2011) • Factors shaping the adoption and evolution of different testing models • The parallel model • The provider model • The provider-parallel model • The support of the medical setting	Credible	"It had nothing to do with HIV screening at all. I'm an emergency medicine physician and I like to make diagnoses and I got frustrated because I would see patients that I was convinced had an AIDS-defining illness or clinical stigmata of AIDS and I couldn't make a definitive diagnosis in the emergency department." Christopoulos (p. 3) "It was always a struggle to get them to routinely offer … .this patient looks a little too sick. They would definitely profile who they would ask [to be tested], so we didn't get true screening by having the nurses do it. They would definitely look at a little old lady and probably not offer it to them." Christopoulos (p. 3) "I think that as awkward as it is to get a diagnosis of HIV this is the ultimate health-care setting, right? This place is crawling with doctors and we've got specialists and you're here and we're gonna help you. And I think that as lonely as it might be getting that diagnosis you're also surrounded by – this is an environment that just bleeds medicine, right? I mean, I kind of think it's almost like an ideal situation." Christopoulos (p. 7) "I believe the ED is where folks are coming for emergency care and so I think that whatever they're presenting with is what their issue is at that time. I think that HIV, even though it might be a very important diagnosis to me and everybody else up in there-you know what I mean-I think folks are still wanting to come in to be serviced for what they came in for, you know. And so I think that we should never forget that and that even though it's very important to us the HIV clinic should be another referral." Christopoulos (p. 7)

(*Continued*)

Table 2. Continued.

Synthesized themes and original subthemes	Credibility Score	Illustrative quotes
Systems Horwood et al. (2010) • Recording of clinical findings in the patient record card • Inadequate training • Enabling factors for implementation	Unequivocal	"According to South African what–what, there is something that says you cannot suspect someone is positive. So you cannot say that this child is positive, whereas the child has not tested, and you have to write on the card 'symptomatic of HIV' and they have not tested." Horwood (p. 316) "It [talking about HIV] is difficult and needs skills. Everyone should have done VCT [voluntary counselling and testing training] so that you have those skills." Horwood (p. 316) "[mothers] knew their status during antenatal care, so it is easy for me. When I do IMCI … I don't even ask their status; I just peruse the card and I just see this is an HIV positive child" Horwood (p. 317)

congruent with current HIV knowledge and practice. Their statements often revealed paternalistic attitudes toward their patients. Some HCP comments indicated that HIV-related stigma affected their decision-making about HIV testing. In addition, this review found that system factors such as time, training, and resources both facilitated and hindered opt-out HIV testing.

A common attitude among HCPs was the outdated notion that HIV is a terrible disease that equates to certain death. This was evident in Christopoulos' study, in which a HCP was more comfortable disclosing the death of a child than a positive HIV result. This HCP's attitude reflected the ongoing stigma toward HIV infection (Gostin, 2006). However, because of the availability of anti-retroviral medications (at least in developed countries and increasingly in developing countries), HIV is no longer a death sentence. Research shows that if patients engage with HIV treatment at an early stage in their infection, they are more likely to live a normal life span with normal immune function (Grinsztejn et al., 2014; Okulicz et al., 2014).

In developing countries, HIV is still a major health threat due to lack of access to anti-retroviral medications, and stigma and discrimination are prevalent (Csete, Schleifer, & Cohen, 2004; Haji, Deressa, Davey, & Fogarty, 2014). This may account for HCPs' concerns and render opt-out testing less feasible and possibly unethical (April, 2010; Csete et al., 2004; Rennie & Behets, 2006). If HIV treatment is not available, opt-out HIV testing may do more harm than good (April, 2010).

Research has shown that when HCPs are not aware of the plethora of opt-out HIV testing guidelines, brief educational interventions can increase the number of HIV tests that they order (Berkenblit et al., 2012; Lubelchek, Hotton, Taussig, Amarathithada, & Gonzalez, 2013). System-related factors identified in this study such as time constraints can be managed by emphasizing testing during non-peak hours and using dedicated staff to perform it (Chen et al., 2011).

The HCPs in the Evans, and Ndirangu, (2011) study stated that merely offering the HIV test implied that the patient had engaged in immoral behaviour. This paternalism diminished patient autonomy, because patients who were excluded from opt-out HIV testing could have benefited from it. On the other hand, paternalism could also cause HCPs to omit offering patients the opportunity to decline the test, so a balance between missing testing opportunities while preserving patient autonomy is necessary (Bulman, Mathews, Parsons, & O'Byrne, 2013; Gostin, 2006). Research shows that most patients prefer shared decision-making (Kumar et al., 2010).

Participants expressed concern about potential patient harm if pre-test counselling was cut short or omitted. Concerns about a lack of pre-test counselling were fear-based and counter-intuitive. In the case of the nurse who feared legal repercussions if she offered an HIV test to a child, it seems more likely that not performing the test in a child suspected of HIV would lead to legal consequences – and could even be construed as negligent if the child were found to be HIV positive (Gostin, 2006).

The HCPs' misgivings about shortened pre-test counselling may have developed from HIV testing practices in the early years of the epidemic, when pre-test counselling and separate written consent were required (Gostin, 2006). Moreover, participants in the African studies had seemingly more experience with giving positive HIV diagnoses, which may have influenced their views on the importance of pre-test counselling. Certainly HCPs should receive training about the legislative requirements for pre-test counselling in their locality, but research shows that pre-test counselling can be safely abbreviated (Buzdugan

et al., 2012). System-related factors such as a dedicated staff member to do the testing and an educational patient video to provide pre-test information have been found to improve testing rates (Burns et al., 2012).

While some HCPs mentioned the lack of pre-test counselling training as a systems-related barrier, they did not discuss post-test counselling, which may be a more important topic for training. With the opt-out approach, some HIV-positive results will be unexpected, requiring coping abilities that patients may not have (Galletly, Pinkerton, & Petroll, 2008). Given that being diagnosed with HIV can lead to stigma, discrimination, depression, and even intimate partner violence, HCPs should be trained to include harm minimization strategies in post-test counselling (Galletly et al., 2008; Maman et al., 2002).

Only one study highlighted the positive aspects of opt-out HIV testing (Christopoulos et al., 2011). In this study, HCPs highlighted the professional satisfaction that arose from making an HIV diagnosis. Moreover, the HCPs found the ability to provide immediate connection to HIV care to be an affirming experience, particularly for patients who would not otherwise have access to HIV testing. One participant discussed the benefits beyond health that were achieved through opt-out testing, such as connecting homeless individuals to housing (Christopoulos et al., 2011). This commitment to supporting marginalized patients' well-being suggests that HCPs who were guided by social-justice principles were more supportive of the opt-out approach (Powers, 2006). The HCPs in this study were also most knowledgeable about the present state of HIV treatment and testing recommendations and tended to view opt-out testing positively. This suggests a connection between knowledge of current evidence and clinical practice (Hunter, Perry, Leen, & Premchand, 2012).

Several factors limited the findings of this review. Relatively few articles were eligible for inclusion, and empirical studies were not reviewed. Moreover, the participant numbers in the reviewed articles were relatively small and may not represent the entire spectrum of HCP experiences with opt-out HIV testing. Whilst the studies were heterogeneous in terms of geographical location, cultural context, clinical setting, HCP specialty, and HIV prevalence, the themes extracted may not represent the HCP experiences with opt-out HIV testing in other settings in which it occurs.

HCPs should be empowered to offer HIV testing without having to worry about legal action, perpetuating stigma, or causing patients to disengage with care. To achieve this, HCPs require up-to-date, evidence-based information about the current status of HIV diagnosis and treatment, including local prevalence data and the medical justification for the opt-out approach. Recommendations for opt-out HIV testing should be disseminated to HCPs in a broad range of settings. Implementation of system-related factors such as electronic reminders and care coordination procedures should be considered, and a social-justice commitment among HCPs should be encouraged.

Disclosure statement

No potential conflict of interest was reported by the authors.

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Appendix 1. Study screening tool

Checklist for assessing the quality of qualitative studies.
Title:
Author(s):
Year:

Criteria	Yes (2)	Partial (1)	No (0)
1. Question/objective sufficiently described?			
2. Study design evident and appropriate?			
3. Context for study clear?			
4. Connection to a theoretical framework/wider body of knowledge?			
5. Sampling strategy described, relevant and justified?			
6. Data collection methods clearly described and systematic?			
7. Data analysis clearly described and systematic?			
8. Use of verification procedure (s) to establish credibility?			
9. Conclusions supported by results?			
10. Reflexivity of the account?			

From Kmet, L. M., Lee, R. C., & Cook, L. S. (2004). *Standard quality assessment criteria for evaluating primary research papers from a variety of fields.* Alberta Heritage Foundation for Medical Research.

Appendix 2. JBI-QARI data extraction form

Qualitative Data Extraction Tool
Author:
Journal:
Year:
Reviewer:

Methodology
Method
Data Analysis
Setting & Context
Geographical Context
Cultural Context
Participants: ***Number:*** ***Description:***
Phenomena of Interest

Findings	***Narrative Description***	**Qual. Evid. Rating 1,2,3**
Authors conclusion/Comments		

Rationale and aims for this integrative review

Integrative literature reviews organise, synthesise and critique published research. A variety of methodologies (e.g., case studies, original research, and theoretical articles) are analysed to form a new understanding of a phenomenon and are typically broader than other types of reviews, such as meta-analyses or systematic reviews (Whittemore & Knafl, 2005). This integrative literature review aimed to:

1. link the two literature review publications and the rest of the thesis through a critical discussion of the research underlying this thesis; and
2. present the gaps in knowledge and unresolved issues about opt-out HIV testing in Australia, establishing the foundation for the final study in this thesis.

By expanding on the evidence and concepts described in the published articles, this review provides an in-depth analysis of the current state of knowledge about opt-out HIV testing.

Literature searches

The objectives of the literature search were to compare Australian and international HIV testing practices, summarise the research on opt-out HIV testing to date, and identify the gaps in knowledge about opt-out testing in Australia. The search strategy approach was adapted from PRISMA guidelines (Moher, Liberati, Tetzlaff, & Altman, 2009). See Figure 2. Literature searches were limited to publication dates ranging from 2006-2016. The time frame was based on the year (2006) that the US Centers for Disease Control released its recommendation for opt-out HIV testing in the general population, forming the basis for many research articles on the topic. Databases were selected for this search if they included concepts pertaining to HIV, such as medicine, nursing, and social sciences. The search engines Ovid and ProQuest were used to search their respective databases. Medline, Science Direct and CINAHL were searched between July and August 2016 (using the keywords detailed in Figure 1) to ensure relevant articles were discovered. Due to the large volume of articles about HIV (1888), terms related to the basic science of HIV, treatment, vaccine development, and other types of testing were excluded. Although they may have described interesting issues relevant to this thesis, articles about opt-out HIV testing in specific populations (such as pregnant women) were excluded because the present research aimed to evaluate opt-out HIV testing in a general adult population rather than specific groups. Search terms were exploded to capture the varied terms for opt-out testing that appeared in the literature (such as "provider-initiated" or "non-targeted" testing). Reference lists of the retained articles were hand searched to identify additional relevant articles, including high-impact or highly cited articles (original research, theoretical papers, and commentaries) published before 2006. Grey literature was identified from the retained articles' reference lists and gathered by internet search engine. Full-text review was conducted on the remaining 500 articles. Following the full-text review, 71 articles about important concepts underlying opt-out HIV testing (such as classification error, consent, and pre-test counselling) were included in the review.

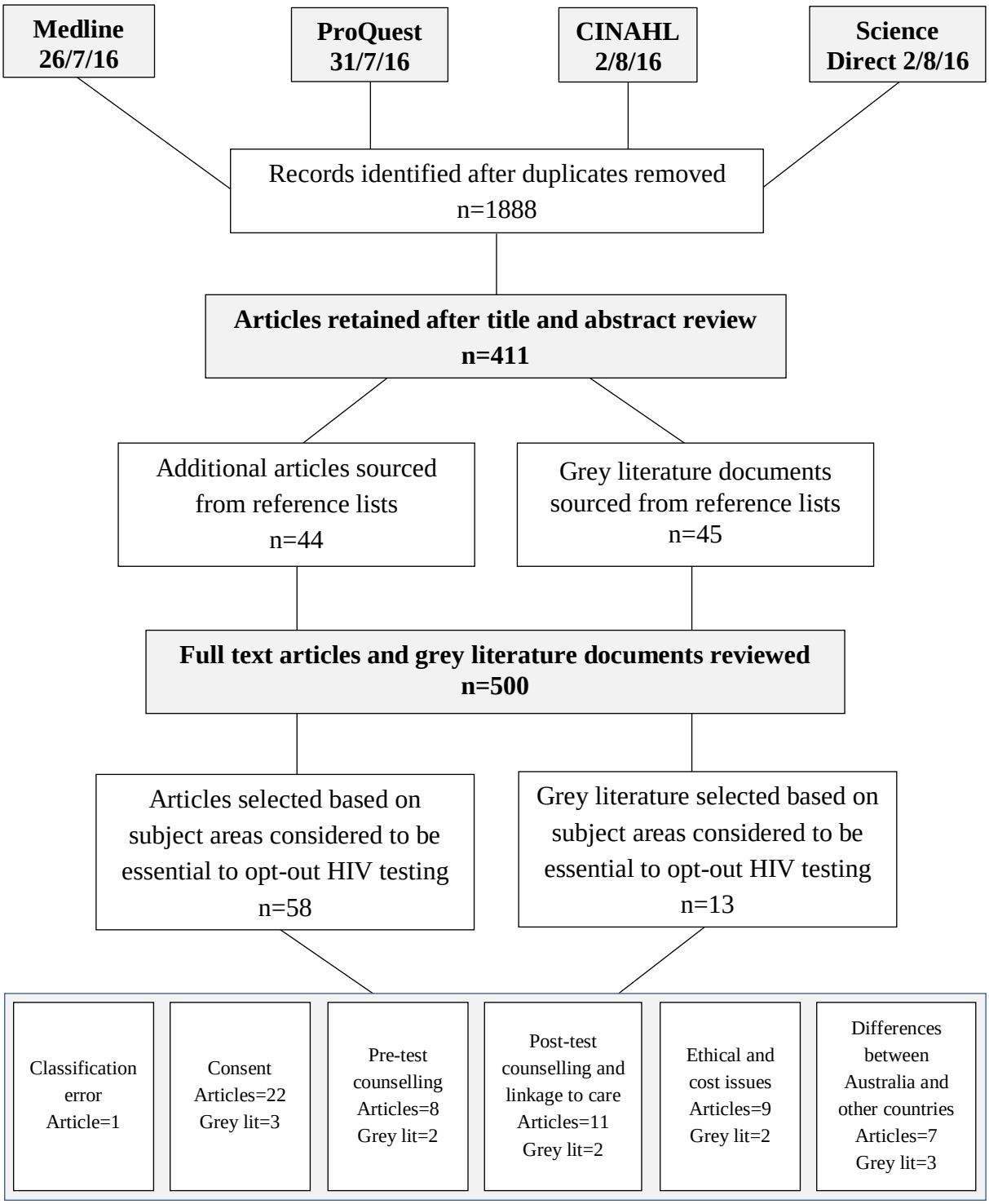

Figure 2. Literature search results, adapted from PRISMA (Moher et al., 2009)

Research about other issues with opt-out HIV testing

As previously noted, the first two publications for this thesis focused on the potential advantages of opt-out HIV testing in Australia. To present a complete picture of the current state of knowledge, research about the disadvantages of opt-out HIV testing is emphasised.

This section addresses common unexpected consequences and problems that have been described in the literature on opt-out HIV testing, such as classification errors, difficulties with consent and pre-test counselling, and stigma.

Classification errors

One risk of opt-out testing is known as an "error of classification", first posited by Johnson and Goldstein (2003) in a seminal paper about opt-out organ donation (Johnson & Goldstein, 2003) (p.1339). The researchers found that defaults produced a robust benefit for organ donation (e.g., opt-out organ donation increased the number of donations compared to an opt-in approach). The authors cautioned that defaults could result in misclassification, where people are identified as organ donors against their wishes. Conversely, the opposite misclassification occurs when people want to be donors, but if the situation arises, their organs are not donated.

Classification error is pertinent to defaults in other health-related situations. In the case of opt-out HIV testing, a classification error occurs if a patient who does not want to be tested is tested, or if a patient who wants to test is left out. If misclassification occurs, people at highest risk of HIV may not test, limiting the health benefits of the opt-out approach. Conversely, people may accept opt-out HIV testing, realising later that they were not ready for testing at that time.

Johnson and Goldstein's (2003) findings in relation to organ donation may not apply to opt-out HIV testing. Unlike HIV testing, organ donation benefits other people (organ recipients) directly, whereas the public benefits of opt-out HIV testing, such as potentially reducing transmission, may not be apparent for years. Accordingly, the authors argued that defaults may not be as effective for interventions that create emotional responses. Organ donation does not typically result in stigma or discrimination like HIV, with the latter possibly resulting in a greater emotional cost.

One strength of Johnson and Goldstein's study was its triangulation of experimental and observational data. First, they performed an online experiment in relation to organ donation with opt-in, opt-out, and neutral conditions, demonstrating the impact of defaults on hypothetical decision-making. Then they analysed observational data about organ donation rates in countries with opt-in versus opt-out approaches, which supported the experiment's findings. Although many subsequent studies across many clinical applications have built upon Johnson and Goldstein's work, highlighting the risk of misclassification, this literature search did not find any studies about opt-out HIV testing that specifically tested for classification error. However, several studies about HIV testing

have built upon Johnson and Goldstein's work (Montoy, Dow & Kaplan, 2016; Zetola et al., 2008).

Problems with consent

Opt-out HIV testing omits separate written consent. By signing the general consent for treatment, patients agree to HIV testing, but still need to understand what the testing process entails. The CDC recommended that patients must be informed 1) that they are going to be tested, and 2) that they have the right to refuse testing (Branson et al., 2006). Although removing separate written consent for HIV testing streamlines the testing process, verbal consent for the procedure is still required, a process comparable to other routine testing procedures. For example, whilst a Pap smear would be covered by the general consent for treatment, providers would obtain verbal consent before doing a Pap smear. Separate written consent may be valuable for health care providers because it provided evidence that the patient made an informed decision (potentially decreasing liability risk). However, research showing increased liability for providers performing opt-out HIV testing was not identified.

Historically, aiming to decrease stigma, AIDS activists took a patient-rights perspective on consent, elevating patient autonomy above all other considerations. After effective HIV treatment became available, paediatricians were the first group to challenge consent procedures. They argued that the process of separate consent and pre-test counselling was too onerous and would decrease HIV testing rates. They believed that health care providers had an obligation to protect infants from HIV transmission during birth, and this overruled mothers' right to decline to test (Bayer & Fairchild, 2006).

Research found that eliminating separate written consent for HIV testing led to more testing, particularly among groups at highest risk for HIV. An observational study conducted by the San Francisco Public Health Department found that eliminating separate consent increased testing rates and detection of HIV infections in homeless and uninsured men who tested infrequently (Zetola et al., 2008). However, this study was conducted only a few months after the policy was implemented, as such it was unclear if the effect was sustained over time or if the study duration (12 months) was long enough to capture adverse events.

Research suggests that even if the opt-out approach increased HIV testing rates, many researchers encountered problems with consent. Several studies suggested that without separate written consent, opt-out HIV testing was not always voluntary. A mixed-methods study undertaken in Kenya found that patients often believed that they could not

refuse opt-out HIV testing (Njeru, Blystad, Shayo, Nyamongo, & Fylkesnes, 2011). A strength of this study was its 93% survey response rate. In a study from another African country, patients commonly believed that opt-out HIV testing was coercive; indeed, doctors admitted that they did not always inform patients that they were going to be tested (Evans & Ndirangu, 2011; Hardon et al., 2011). A qualitative study of health care providers in a Spanish opt-out HIV testing program found that participants tested some patients for HIV without the patients' knowledge (Navaza, Abarca, Bisoffi, Pool, & Roura, 2016). However, the researchers reported that they did not reach data saturation, so other attitudes could have emerged. There was no evidence from low-prevalence countries like Australia that patients were unknowingly tested for HIV, but these findings demonstrated that health care providers could overlook their obligation to gain patient consent before performing opt-out HIV testing.

The power imbalance between health care providers and patients could also affect consent for opt-out HIV testing. Some researchers suggested that patients thought they could not refuse testing because health care providers were in a position of authority (Celada, Merchant, Waxman, & Sherwin, 2011). Bayer and Fairchild (2006) stated that opt-out HIV testing was "ram[ming] an HIV test down people's throats without permission." (p.649) (Bayer & Fairchild, 2006). Abhyankar (2014) suggested that opt-out testing uptake could be improved by giving patients more information about the risks and benefits of the options, and by emphasising their right to decline testing (Abhyankar, Summers, Velikova, & Bekker, 2014).

Some studies found patient support for opt-out HIV testing without consent. A survey of US prison inmates who had opt-out HIV testing found that patients often misunderstood the difference between opt-out and involuntary testing: over 40% thought that the testing was mandatory. However, a majority (85%) of the inmates thought that HIV testing *should* be mandatory, although the World Health Organization opposes mandatory testing in any circumstance (World Health Organization, 2012). A drawback of this study was that researchers did not control for the variation in the way nurses offered the test (e.g., some nurses were observed to use active choice language such as "would you like an HIV test?" instead of opt-out) possibly influencing prisoners' beliefs about whether testing was voluntary. The survey results alone did not provide an explanation for these beliefs. Qualitative interviews exploring attitudes and beliefs about consent might have enriched the findings. Nonetheless, this study provided more evidence that health care providers may need to explain the fundamental difference between opt-out testing and mandatory testing (Rosen et al., 2015).

A similar issue that surfaced in the literature was patients' mistaken assumption that they were tested for HIV during a health encounter. A British study found that 38% of surgical patients thought they had been tested for HIV during their preoperative evaluation when in fact they had not. The patients did not receive any test results from the evaluation, yet 93% assumed they had a negative HIV test. If people assume they do not HIV, they may forgo further testing or continue high risk behaviours, potentially leading to more HIV transmission (Albrecht et al., 2012). A noted limitation of this study is that the questionnaire did not ask the participants why they thought they were tested for HIV. The idea that health care providers needed to inform their patients when HIV tests were *not* performed was unique among the articles in this review.

Consent in special situations

Most research on opt-out HIV testing was conducted in primary care, jails, or emergency settings. Few studies investigated opt-out HIV testing when the patient was not competent to make health care decisions. The CDC guidelines did not describe opt-out HIV testing for patients who were intoxicated, unresponsive, unable to speak or understand the dominant language, or gravely ill.

The exclusion criteria varied across the opt-out HIV testing programs included in this review, limiting the ability to generalize from their findings. Several studies from emergency departments did not state if incapacitated patients were excluded from opt-out HIV testing due to their inability to give consent (Arbelaez et al., 2009). In some studies, only patients arriving through triage were tested, perhaps based on an assumption that patients arriving by ambulance could not provide consent (though this was not explicitly stated) (Brown, Shesser, & Simon, 2007). Other researchers reported that extremely unwell patients were excluded because they could not give informed consent (Haukoos et al., 2009; Sattin, Wilde, Freeman, Miller, & Dias, 2011). A jail-based opt-out HIV testing program excluded inmates with active suicidal ideation, but did not mention other common symptoms (such as hallucinations) that would make consent difficult to obtain (Kavasery et al., 2009). One US study suggested that excluding mentally ill people from opt-out HIV testing represented a missed opportunity. After changing laws to allow opt-out testing in inpatient psychiatric facilities, HIV testing increased by 60% from previous years in one facility (Weller, Levitt, Myers, Riley, & Gesmundo, 2016). It was not clear if other psychiatric facilities showed a similar increase.

A qualitative study of opt-out HIV testing in a critical care unit found that providers and families were frustrated when HIV testing was clinically indicated but consent could not

be obtained. Interviews and focus groups were conducted among discharged critical care patients, family members, and health care providers, providing a range of perspectives. Participants suggested that specific guidelines for HIV testing in critical care should be developed (Martin et al., 2015). This study was conducted in South Africa, a high HIV prevalence country, so it may not be transferable to other settings. An ethical analysis concluded that if possible, competency to make decisions should be assessed before opt-out testing occurs (Hanssens, 2007). Some researchers recommended that when a patient was under sedation or on mechanical ventilation, opt-out HIV testing should be performed with consent from a family member or health care proxy. Opt-out HIV testing by proxy was not addressed in the literature, but could be beneficial in critical care settings, where knowledge of HIV status is paramount (Blackwell & Guido-Sanz, 2016).

Another theme in the reviewed literature related to opt-out HIV testing among migrants. In migrant health services, there is a power imbalance and unequal knowledge between provider and patient (influenced by culture and language) that could complicate the issues around consent for opt-out HIV testing. A study from Belgium found that GPs were less likely to perform opt-out HIV testing on migrants due to ethical concerns, reasoning that migrants might not have access to care if they tested positive for HIV (Manirankunda, Loos, Debackaere, & Nostlinger, 2012). Although Australia's Seventh National HIV Strategy 2014-2017 designated migrants as a priority population for HIV prevention and education, there was a lack of evidence about how to meet their needs (Australian Government Department of Health and Ageing, 2014). A systematic review of HIV testing of migrants in high income countries did not find any Australian research on the issue (Alvarez del Arco et al., 2013). People with HIV are generally not eligible to migrate to Australia, and all migrants aged 15 or older who are applying for permanent visas are required to be tested for HIV (although refugees and other humanitarian entrants may qualify for a health waiver) (Australian Government Department of Immigration and Border Protection, 2016).

Another unsettled issue pertinent to all countries is whether victims of sexual assault should have opt-out HIV testing. No studies addressing this scenario were found in the literature searches. It is not known if patients or health care providers would find the opt-out approach to be acceptable in post-sexual assault clinical encounters. Extra caution may be required to ensure that HIV testing would not be coercive. If opt-out HIV testing is implemented in Australia, special consideration should be given to this situation.

Stigma and discrimination, domestic violence

Researchers posited that the risk of stigma and discrimination from HIV testing may be diminished with the opt-out approach (Abdool Karim, 2011; White et al., 2015; Wynia, 2006). Many studies reported that HIV stigma is prevalent. For example, numerous studies reported that women with HIV had an increased risk of being a victim of intimate partner violence, though these studies were conducted in the US or sub-Saharan African countries and may not apply to Australia (Durevall & Lindskog, 2015; Hatcher et al., 2016; Njie-Carr, 2014). A US study of HIV-positive people found that 73% had experienced intimate partner violence, and 29% believed that the violence was provoked by their HIV status (Ramachandran, Yonas, Silvestre, & Burke, 2010). However, it must be considered that this was a small pilot study in an urban setting and may not apply to larger segments of the population or to rural areas.

Research identified an association between intimate partner violence and HIV. An integrative review of HIV risk in abusive heterosexual relationships found that the male often refused to use a condom and the woman was unable or afraid to persuade him to do so (Phillips et al., 2014). The study did not identify causality or temporal relationships between intimate partner violence in HIV infection. In a US survey that controlled for age, gender, and HIV risk behaviours, women with abusive partners were less likely to test for HIV even if at risk (Nasrullah, Oraka, Breiding, & Chavez, 2013).

Numerous research studies have shown that HIV-infected people continue to experience discrimination (Chambers et al., 2015), including Australian people living with HIV (Slavin, 2012). Even if most of their experiences with the health care system were positive, most HIV-positive people experienced episodes of discrimination, such as being asked by health care providers how they contracted HIV. A study from the US showed that 25% of HIV-infected patients thought their health care providers discriminated against them after learning of their status. Although this study was conducted before opt-out HIV testing was recommended, the sample was nationally representative and could be generalised to the larger population (Schuster et al., 2005).

In a study of HIV stigma in Quebec, researchers interviewed HIV-infected people about their interactions with health care providers. The participants described behaviours that reflected health care providers' stigmatised beliefs, like donning excessive personal protective equipment (such as face masks) to care for them (Gagnon, 2015). A study of general practice patients in Britain found that opt-out HIV testing was acceptable, but patients feared they would be profiled based on their personal characteristics (such as sexual orientation). Fear of

ostracism could lead to decreased testing rates, particularly among high risk groups that tend to be stigmatised. Findings from this study were not definitive because the sample did not include men over age 25 who had sex with men, one of the main groups that the authors believed should undergo opt-out HIV testing (Glew, Pollard, Hughes, & Llewellyn, 2014).

In a study that compared patients' experiences with opt-in and opt-out testing, the authors hypothesised that because risk-based HIV testing commonly excluded heterosexuals or non-drug users, these groups were less likely to be tested. The researchers found that most patients thought the routine offer of an HIV test was less stigmatising than having to ask to be tested. On the other hand, some patients said that opt-out testing singled them out because of their personal characteristics (the opposite of what opt-out HIV testing intended to do). But if the health care provider reassured patients by saying, "we are testing everyone", they were more likely to accept testing. Some patients even stated that their peers (who did not perceive themselves to be at risk for HIV) should have had opt-out testing. One strength of this study was the relatively large number of interviews (50). However, the participants were males aged 18-24, so it is unknown which approach would be acceptable to women or other age groups. Although the sample was limited, making it difficult to generalise, this study demonstrated that the opt-out approach made HIV testing an unexceptional, non-stigmatising experience. Moreover, it identified a simple statement that could be added to opt-out HIV testing programs ("we are testing everyone") that decreased stigma and increased test acceptance (Knight, Small, & Shoveller, 2016).

Some studies found that opt-in HIV testing was associated with stigma as well. A US social psychology study gave participants a fabricated cover story about a stigmatised disease and then offered them hypothetical opt-in or opt-out testing. The researchers found that the opt-in approach was associated with reluctance to test because participants feared their behaviours would be construed as immoral. Opt-out approaches were associated with fear of ostracism or moral approbation for *not* testing (e.g. if people were not willing to test, they were assumed to be HIV-positive). The participants were more likely to test for the stigmatised disease if testing was offered as an opt-out rather than an opt-in. While this experiment had limited external validity (it was conducted among healthy university students in San Francisco and used a fabricated, hypothetical case) it identified an association between opt-out approaches and peer influence (Young, Monin, & Owens, 2009).

Whilst the previously mentioned studies indicated that opt-out HIV testing was less stigmatising than opt-in testing, other research found the opt-out approach did not decrease stigma. A study of patients in a Los Angeles clinic explored the effect of the two

approaches on HIV-related stigma. Immediately after they were offered HIV testing during a routine health care encounter, patients were asked if they were offered an HIV test and whether it was presented as an opt-in or opt-out. The patients then completed a questionnaire regarding their beliefs about HIV and stigma. The opt-out approach increased testing rates but did not decrease stigmatised beliefs as measured by the questionnaire (Mahajan et al., 2016). A strength of this study was its high response rate (86%). The researchers suggested that the health care providers should have offered more HIV education before testing to decrease stigma, although it would have been inconsistent with the concept of opt-out testing, which omits pre-test counselling. Overall, the opt-out approach achieved its goal of increasing HIV testing rates. Several studies found that opt-out HIV testing decreased (or at least did not increase) stigma, but the study by Majahan (2016) highlighted the limitations of the opt-out approach in changing entrenched beliefs about HIV.

Researchers reported that in areas where HIV was highly stigmatised, people often avoided health care services to protect their privacy. In a survey of 1400 Nigerian men, a significant number agreed that attending health services signalled to the community that he was HIV-positive, leading to social distancing (Akanle, 2008; Celada et al., 2011). A systematic review of stigma and HIV testing found that in some countries (especially in sub-Saharan Africa) requesting an HIV test was an admission of promiscuity and therefore avoided (Mahajan et al., 2008).

In a study conducted in Kenya and Uganda, researchers found that when both opt-in and opt-out HIV testing were available, couples tended to self-sort. If one partner chose opt-out testing, the other partner typically chose opt-in testing (Hardon et al., 2011). A strength of this study was that it encompassed a variety of methods: direct observation, interviews with patients and health care providers, and focus groups of HIV-infected people. Opt-out HIV testing could be the initial step in a sequence of testing strategies that are modified based on sexual networks, (e.g. opt-out testing in the general population followed by targeted testing of the partners of HIV-infected people).

Another finding from this study related to patients' beliefs about local health services. Some patients made their decision to have HIV testing based on the quality of care they thought they would receive if they tested positive for HIV (Hardon et al., 2011). Although this study was conducted in Kenya and was not generalizable to a well-resourced, low prevalence country like Australia, it raised an issue that the current Australian literature did not address: whether the expected quality of HIV care affected testing rates.

The weight of the evidence showed that opt-out HIV testing increased testing rates and sometimes (but not always) decreased stigma about the infection. Regardless of testing strategy, HIV-related discrimination and violence remained problematic across a range of settings. Some researchers suggested modifications to the opt-out approach (such as changing the wording of the opt-out offer) to address these issues.

Pre-test counselling

As previously discussed, opt-out HIV testing in the general population omits or abbreviates pre-test counselling. Nonetheless, the 2006 CDC guidelines (Branson et al., 2006) were more nuanced than the first wave of research on opt-out HIV testing suggested. The guidelines stated that "Patients found to have risk behaviors (e.g., MSM or heterosexuals who have multiple sex partners, persons who have received a recent diagnosis of an STD, persons who exchange sex for money or drugs, or persons who engage in substance abuse) and those who want assistance with changing behaviors should be provided with or referred to HIV risk-reduction services (e.g., drug treatment, STD treatment, and prevention counselling)." (Branson et.al., 2006). In other words, high-risk individuals could benefit from pre-test counselling, though this message was sometimes absent in studies about opt-out HIV testing.

Although several Australian recommendations about pre-test counselling were identified for this integrated literature review (Australasian Society for HIV Medicine, 2014; Government of Western Australia Department of Health, 2012), there was no guidance about the amount of time required to perform adequate pre-test counselling or how to measure its quality. Australian recommendations did not question the effect of pre-test counselling on health outcomes, efficiency or cost, although international evidence suggested minimal benefit.

A US study randomised patients to pre-test counselling (including information about HIV and risk reduction advice) or no counselling, prior to HIV testing (Metsch et al., 2013). The researchers found that staff time, training, and quality assurance activities associated with pre-test counselling significantly increased costs. Six months after the intervention, pre-test counselling had not decreased the incidence of sexually transmitted infections, including HIV. A strength of this study was its high retention rate (86.5%) between the intervention and follow-up testing (although incidence was only tested at six months, so it is not known how if the effect would last beyond that time frame). A commentary on the same study suggested that health care providers did pre-test counselling primarily to feel like they were "doing something as opposed to nothing", reflecting their tendency to continue ineffective or

inefficient practices (Haukoos & Thrun, 2013 p.1681), though the authors did not test this idea empirically.

The limitations of pre-test counselling can also be viewed through a conceptual framework called the Health Impact Pyramid (Frieden, 2010). Frieden posited that compared to improvements in the social determinants of health (such as better living standards or access to healthy food), counselling is the most time-intensive health intervention with the smallest benefit to the general population. Counselling is not only the least effective modality for improving population health, it is also a barrier to positive health outcomes. Smoking cessation is a prime example. Only 10% of smokers quit in response to education; more people quit smoking because of "nudges" like smoke-free workplaces or tobacco taxes (Frieden, 2010).

In the case of HIV, pre-test counselling historically included education about the use of condoms for prevention (Jones & Mitchell, 2014). Like smoking cessation, research has shown that education about condoms was not as effective as changing the social norms to make condom use more common (Frieden, 2010). An example of this principle was Australia's success at achieving universal condom use among sex workers. Advocacy and peer education (not education from individual health care providers) led to condom use becoming the norm rather than the exception (Bates & Berg, 2014). Therefore, per the Health Impact Pyramid and its evidence base, pre-test counselling (which is resource-and time-intensive) could be reconsidered.

In contrast, some research suggested that pre-test counselling may be required or desirable for patients in at least some instances. A study of an opt-out HIV testing program in Spain found that some patients had erroneous information about HIV and HIV testing, suggesting that pre-test counselling might be helpful for people with low baseline knowledge about HIV (Navaza et al., 2016). However, it must be considered that the sample for this study included only migrants to Spain from Latin America, so their knowledge base could have differed from Spaniards or other Europeans. Pre-test counselling may have helped the migrants to understand HIV testing, possibly influencing their decision to test.

Another study interviewed Belgian general practitioners about opt-out HIV testing among migrants from sub-Saharan Africa. Participants stated that patients preferred the option to have pre-test counselling rather than have it skipped entirely (Manirankunda et al., 2012). A drawback of this study was that the migrants themselves were not interviewed. However, the general practitioners' views indicated that opt-out HIV testing routine could accommodate different patient needs by offering pre-test counselling as an opt-in.

Pre-test counselling is typically done only when HIV testing occurs in clinical settings. Home-based HIV testing kits are already available in some countries (Paltiel & Walensky, 2012). One Australian company applied to the Therapeutic Goods Administration for approval of a home HIV test (Medew, 2016). An Australian survey of gay men found that the majority would choose home-based HIV testing over testing in health services or at non-health venues such as nightclubs (Yang et al., 2014). Preferences of the broader population are not known because the survey did not include heterosexuals or women, but home-based testing might appeal to a range of people. Whilst some people may continue to seek HIV testing in health care settings, the findings from Yang (2014) (coupled with advances in testing) point to a diminishing role for pre-test counselling (Haukoos & Thrun, 2013).

Whilst Australian guidelines recommend pre-test counselling before HIV testing, evidence showed that the practice is costly and does not increase testing rates. Counselling may be an ineffective strategy for improving population health outcomes. Other research indicated the benefits of pre-test counselling for groups with less knowledge about HIV.

Post-HIV test counselling

Opt-out HIV testing can alter people's responses to an HIV diagnosis. Because opt-out HIV testing is conducted as part of a routine health encounter that typically addresses other health issues, patients may not have considered the implications of the HIV test. Some commentators suggested that patients who had opt-out HIV testing were more likely to be shocked by a HIV-positive diagnosis than if they had requested the test (Galletly, Pinkerton, & Petroll, 2008). There was no consensus in the research as to whether opt-out HIV testing caused a different degree of emotional stress than opt-in testing.

Some studies on opt-out HIV testing considered the ethical issues that could arise after a patient tested positive for HIV. Researchers have identified examples of effective and ethical post-HIV test programs. Hardon (2011) described a "supermarket" in Kampala, Uganda that housed many services for HIV positive people, including youth services, support groups, access to contraception and assistance with medications (Hardon et al., 2011). Higher income countries also had examples of effective programs for HIV-positive people identified through opt-out testing programs (Parker et al., 2016; Tanner et al., 2016).

Post-test counselling is a critical part of opt-out HIV testing programs. Australian HIV organisations have broadly similar recommendations for post-test counselling that typically includes education about HIV laws and the patient's responsibility to not transmit

the virus (Australasian Society for HIV Medicine, 2016). In Australia, failure to disclose HIV-positive status can be considered a criminal act, and there have been numerous prosecutions (Cameron & Godwin, 2014). However, a research-based best practice guideline for post-test counselling in opt-out HIV testing programs has not been tested or standardised.

Failure to convey results and testing without linkage to care

Testing for HIV without linkage to HIV care is considered unethical (World Health Organization, 2012). In opt-out HIV testing, a subgroup of patients may not return for their HIV test result or may be lost to follow up, with consequences for the individual and public health. Delay in linkage to HIV care or inadequate case management could result in legal problems for health services and health care providers. Patients could theoretically bring a malpractice lawsuit because they were not informed they were being tested for HIV, did not consent, or did not fully understand the consequences before testing. Opt-out HIV testing programmes should include a protocol for post-test counselling, linkage to care, and funding for both (Hanssens, 2007).

A South African study explored differences in linkage to care between opt-in and opt-out HIV testing. At 12-month follow up, only two-thirds of the opt-out patients were linked to care, showing that the opt-out approach did not improve the time to CD4 testing (a marker of engagement with HIV care). Poor linkage to care did not necessarily result directly from the opt-out approach because the participants were not randomised and the proportion of patients who returned for their results was not reported. A low number of patients returning for results would have reduced the number of people who engaged in HIV care. The authors suggested that opt-out HIV testing programs should develop a patient call back system to reduce the number of people who were lost to follow up (Leon et al., 2014). An Australian commentary stated that linkage to care for HIV-positive people could be coercive, arguing that patients have the right to refuse treatment, though this argument was not supported by empirical evidence (Cameron & Godwin, 2014).

Research commonly found that receipt of results and linkage to care for people with newly-diagnosed HIV was problematic (Christopoulos et al., 2011; Seth, Wang, Collins & Belcher, 2015). One solution to the problem of poor follow-up was using rapid point-of-care HIV tests (which were approved in Australia in 2012) (Chan et al., 2015). Funding was also a major determinant of follow up, although non-governmental funding in the US showed promise in improving linkage to care (Sanchez et al., 2014). Numerous studies of opt-out HIV testing were conducted in US emergency departments (EDs) because they received CDC

funding to implement and evaluate the approach. Funding typically allowed for case workers to coordinate receipt of test results and linkage to care (Haukoos et al., 2011). Although these studies may not be relevant to Australian EDs because of variations in funding and referral systems, some barriers to ED-based HIV testing were common to both countries (such as limited resources and competing health priorities).

Ethical issues

Ethical issues surrounding opt-out HIV testing have generated research and commentary, although most articles on these topics were from outside Australia. One study compared health care providers' opinions on the ethics of opt-out testing (with general medical consent only and no pre-test counselling), with opt-in HIV testing (which required separate consent and pre-test counselling). Health care providers preferred the opt-out testing method, but patients preferred the opt-in method. These providers also found the 2006 CDC recommendations to be more ethically charged than traditional opt-in testing, but on balance, they thought opt-out HIV testing was reasonable to do. It would be difficult to generalise from this study because it was conducted shortly after adopting the 2006 recommendations and the providers had little experience with the approach (Merchant et al., 2012).

Cost of opt-out HIV testing

Like all health interventions, opt-out HIV testing has an associated cost. Some researchers found that because opt-out HIV testing increased testing rates, providers and administrators feared the approach would lead to over-testing and inefficiency (Celada et al., 2011). A study of opt-in versus opt-out testing from Washington DC (which had a high HIV prevalence of 2.4%) found that both methods were cost-effective at preventing HIV transmission, but opt-out testing was more effective at finding previously unidentified infections. This study also found that opt-out HIV testing was costlier in terms of staff and resources, which contradicted findings from Metsch et al. (2013) that the approach was less costly. The authors point out that cost-effectiveness should not be the most important factor in HIV testing policies because the opt-out approach was superior at identifying HIV infections and averting transmission. Linkage to care costs (such as social workers or case managers who facilitated referrals to HIV services) were another cost of opt-out HIV testing programs, but were not investigated in this study. Although this study was from a high prevalence area not generalizable to Australia, it highlighted the balance required between cost-effectiveness and preventing HIV infections. The study also suggested that a

combination of opt-out and opt-in HIV testing may result in the best cost-effectiveness and health outcomes (Castel et al., 2015).

A cost-modelling study from Canada found that in higher prevalence settings, 80% of the HIV testing budget should be allocated to routine opt-out testing and 20% to targeted testing. The study also found that opt-out HIV testing in lower prevalence settings (hospitals in this case) identified fewer HIV infections than opt-in testing. Unlike other studies in this review, this study did not demonstrate a decrease in HIV risk behaviour after testing. The model also assumed that all HIV-positive people were linked to care although this was not the case. (Research has shown that about 90% of people newly diagnosed with HIV in Australia establish with HIV treatment services within three months, compared to only 40% in the US (Centers for Disease Control and Prevention, 2015; The Kirby Institute, 2014). Cost-effectiveness was best if opt-out HIV testing continued over 10 years, highlighting the need for continuous evaluation and monitoring of opt-out testing programs. The authors recommended that health care providers modify HIV testing methods based on changing dynamics of the local epidemic (Kok et al., 2015).

A cost-effectiveness study in the UK found that opt-out HIV testing was most cost-effective in areas where the HIV prevalence was higher or where testing uptake was greater. Opt-out HIV testing took less time to administer than opt-in testing, resulting in cost savings (Ong et al., 2016). However, this study measured HIV test uptake and its associated cost, not the HIV test offer rate, so it is not known what proportion of the patients opted out. Test uptake between GPs and acute medical units was compared, but researchers did not control for provider-to-provider variation in testing rates within the groups. Providers may have differed in their approach offering opt-out HIV testing.

Another study of opt-out HIV testing in a London acute admissions ward found that it was cost-effective, but findings were based on testing uptake of only 75% (e.g., opt-out HIV testing may not have been cost-effective with 100% uptake). This study ran for only 12 weeks, so it was unclear if cost-effectiveness was sustained over time (Burns et al., 2013). A similar US study found that opt-out HIV testing increased costs, but this was balanced with an increase in identification of HIV infections. The US study was conducted at only one hospital, used only new HIV diagnoses as outcomes, and did not extrapolate the potential cost savings across the lifespan, such as quality-adjusted life years. This study did not capture medical costs that were averted across the lifespan or the costs deferred because of decreased onward transmission (Haukoos et al., 2013). After that study, the same authors developed a risk tool (based on two dimensions: men who have sex with men and injecting drug users) to

target high-risk individuals within the larger population that already had opt-out HIV testing. The risk tool identified more HIV infections compared to opt-out testing without a risk tool, increasing testing efficiency (Haukoos et al., 2013). The authors suggested that after a period of opt-out testing in which a large group of people is tested, it may be appropriate to resume more targeted testing approaches (since the unidentified HIV diagnoses will have been discovered) (Haukoos, Hopkins, & Bucossi, 2014). To date there were no Australian studies on the cost-effectiveness (or cost-benefit) of the opt-out approach to HIV testing.

Differences between Australia and other countries

Despite the benefits of opt-out HIV testing identified in the international literature, this evidence may not apply to Australia. Indeed, a large portion of the research on opt-out HIV testing was done in the US because of funding for evaluation of the 2006 CDC recommendations. Funding from the US also supported some of the research in African countries, which have markedly different HIV epidemics and resources from Australia (Alistar, Grant, & Bendavid, 2014; Reidy et al., 2016). More recently, researchers from European countries such as Ireland, France, Belgium and Portugal investigated the opt-out approach, but it was unclear if their findings could be applied to Australia ((Hall et al., 2015; Manirankunda et al., 2012; O'Connell et al., 2016; The Kirby Institute, 2014; Yazdanpanah et al., 2010; Yazdanpanah et al., 2013).

As noted previously with the linkage to care statistics, there are numerous differences between the HIV epidemics in the US and Australia. For instance, Australia's HIV epidemic is concentrated among urban gay men, whereas US cities such as Newark and Washington DC have generalised HIV epidemics primarily affecting heterosexuals (defined as a prevalence >1%) (Centers for Disease Control and Prevention, 2014). The US has not adopted harm reduction strategies to the same degree as Australia, a world leader in HIV prevention. Needle-syringe programs are less common in the US than Australia, and most US jurisdictions have not de-criminalised prostitution as Australia has done. The two countries' health care systems are essentially not comparable.

Despite these differences, the large scale of the American studies on opt-out HIV testing made them worth examining. The first major trial of opt-out HIV testing was in an emergency department in Denver; researchers used an opt-out approach to test over 28,000 patients for HIV (out of 65,000 ED presentations during the two-year study period). The researchers identified a modest number of HIV infections representing a prevalence of 0.05%. Opt-out testing was cost-effective, acceptable to patients and health care providers,

and did not cause workflow problems (Haukoos et al., 2010). It may come as a surprise that Australia's HIV prevalence (0.15%) is greater than the prevalence in the Denver study. Australia also has the same estimated percentage (14%) of undiagnosed HIV infections as the US (Centers for Disease Control and Prevention, 2015; The Kirby Institute, 2014). While there are likely many differences between Australia and Denver, it is possible that opt-out HIV testing in Australia could have similar outcomes.

Conclusion

The literature review for this thesis commenced with a published scoping review of international literature about opt-out HIV testing. This review found that the opt-out approach could lead to higher testing rates and earlier diagnosis of HIV. Data showed that the incidence of HIV in Australia was increasing, particularly among heterosexuals, possibly due to increased travel to high prevalence areas. More than half of new HIV infections among heterosexuals were diagnosed at later stages, suggesting that an exploration of opt-out HIV testing was needed. The second part of the literature review was a systematic review also presented as a publication. The systematic review synthesised qualitative findings to develop two themes that facilitated or impeded opt-out HIV testing: health care providers' *Attitudes* and *Systems*.

The integrative review then expanded on the literature reviews from the first and second publications, providing a broader context for the present research and addressing topics integral to opt-out HIV testing. Research on opt-out HIV testing was analysed from a variety of perspectives, from consent in special situations to the economic costs of pre-test counselling. Opt-out HIV testing has been implemented and evaluated in a wide range of settings around the world. Research on the approach has been conducted using varied methodologies. There was a paucity of research on opt-out HIV testing among the general adult population in Australia. Although international evidence suggested many potential benefits of opt-out HIV testing, it was unknown if it would be feasible or acceptable to Australian health care providers. This gap in knowledge led to the development of the research project presented in this thesis.

CHAPTER 3

QUALITATIVE STUDY

The first objective of this research project was to describe health care providers' perceived barriers, facilitators, beliefs, attitudes and self-efficacy in relation to opt-out HIV testing. The literature reviews in the previous chapter aimed to synthesise research evidence about health care providers' views on opt-out HIV testing. Findings from this review formed an international context for the research project and laid the foundation for the next study in this thesis, an original qualitative research project about Australian health care providers' views on opt-out HIV testing.

The second objective was to construct health care providers' health belief typology relating to HIV risk and testing in their client population. The publication, Leidel, S., McConigley, R., Boldy, D., Wilson, S., & Girdler, S. (2015). Australian health care providers' views on opt-out HIV testing. *BMC Public Health, 15,* 888. *doi:10.1186/s12889-015-2229-9*, is the first exploration of Australian health care providers' beliefs about opt-out HIV testing. Participants were asked to discuss their beliefs about opt-out HIV testing, revealing themes that went beyond health beliefs. The theory of behavioural economics adds another dimension (testing by default) to the health belief typology.

The methodological approach to this part of the research was qualitative, corresponding to the needs assessment part of the Implementation Science conceptual framework. A qualitative approach was chosen because Australian health care providers' views on opt-out HIV testing had not been examined previously. Their views would offer an initial understanding of provider-sensitive issues that would need to be addressed in the implementation of an opt-out HIV testing program.

Article 3. Australian health care providers' views on opt-out HIV testing.

Leidel *et al. BMC Public Health* (2015) 15:888
DOI 10.1186/s12889-015-2229-9

BMC Public Health

RESEARCH ARTICLE Open Access

Australian health care providers' views on opt-out HIV testing

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Abstract

Background: Opt-out HIV testing is a novel concept in Australia. In the opt-out approach, health care providers (HCPs) routinely test patients for HIV unless they explicitly decline or defer. Opt-out HIV testing is only performed with the patients' consent, but pre-test counselling is abbreviated. Australian national testing guidelines do not currently recommend opt-out HIV testing for the general population. Non-traditional approaches to HIV testing (such as opt-out) could identify HIV infections and facilitate earlier treatment, which is particularly important now that HIV is a chronic, manageable disease. Our aim was to explore HCPs' attitudes toward opt-out HIV testing in an Australian context, to further understanding of its acceptability and feasibility.

Methods: In this qualitative study, we used purposeful sampling to recruit HCPs who were likely to have experience with HIV testing in Western Australia. We interviewed them using a semi-structured guide and used content analysis as per Graneheim to code the data. Codes were then merged into subcategories and finally themes that unified the underlying concepts. We refined these themes through discussion among the research team.

Results: Twenty four HCPs participated. Eleven participants had a questioning attitude toward opt-out HIV testing, while eleven favoured the approach. The remaining two participants had more nuanced perspectives that incorporated some characteristics of the questioning and favouring attitudes. Participants' views about opt-out HIV testing largely fell into two contrasting themes: normalisation and routinisation versus exceptionalism; and a need for proof versus openness to new approaches.

Conclusion: Most HCPs in this study had dichotomous attitudes toward opt-out HIV testing, reflecting contrasting analytical styles. While some HCPs viewed it favourably, with the perceived benefits outweighing the perceived costs, others preferred to have evidence of efficacy and cost-effectiveness.

Background

Opt-out HIV testing is a novel concept in Australia. In the opt-out approach, health care providers (HCPs) routinely test patients for HIV unless they explicitly decline or defer. Opt-out HIV testing is only performed with the patients' consent, but pre-test counselling is abbreviated [1]. This approach to HIV testing uses the behavioural economics concept of default bias, which is the propensity to choose inaction over action [2, 3] Australian national testing guidelines do not currently recommend opt-out HIV testing for the general population. HIV testing in Australia is "opt-in", which means that testing is conducted according to risk factors (such as sexual or drug use practices), clinical indication (such as having another sexually transmitted infection), or by patient request [1]. However, there has been a recent increase in HIV infections in Australia, with the highest number of HIV diagnoses in 20 years recorded in 2013 [4]. In addition, up to 50 % of patients diagnosed with HIV have already developed immune deficiency [4]. An Australian study showed that over half of the people with HIV sought health care in the year prior to their diagnosis [5] which indicates that opportunities to test patients for HIV are being missed. Non-traditional approaches to HIV testing (such as opt-out) could identify HIV infections and facilitate earlier treatment, which is particularly important now that HIV is a chronic, manageable disease [6, 7]. Opt-out testing approaches to other sexually transmitted infections

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like chlamydia, gonorrhoea, and hepatitis B have been found to be cost-effective and acceptable to patients [8–10]. Experimental research has shown that opt-out testing is particularly effective in increasing testing rates and patient acceptance of stigmatised diseases such as HIV [11].

Results published in systematic reviews have shown that opt-out HIV testing is generally acceptable to HCPs [12–14]. However, these reviews were conducted in settings that may not be generalizable to Australia, such as low-and middle-income countries [12] or sub-Saharan Africa [13]. One systematic review of HIV testing in resource-rich countries included three Australian studies, but these studies did not address the opt-out approach or testing in the general population [14]. A US systematic review addressed operational aspects of opt-out HIV testing, which may not be transferable to the Australian context due to differences between the countries' health systems [15]. A review of opt-out HIV testing in Australian antenatal clinics suggested that it was effective (expectant mothers are the only group in which opt-out HIV testing is recommended in Australia), but it may not be applicable to the general Australian population [16]. Despite the plethora of international research on the topic, it is not known to what extent opt-out HIV testing is appropriate, acceptable, or feasible to HCPs in general health care settings in Australia. Two Australian studies indicated that educational barriers (such as a lack of HIV content during training) and operational barriers (such as time constraints) prevent Australian HCPs from seeing HIV as relevant to their practice. Informants also stated that Australian general practitioners should make HIV testing a routine part of their practice [17, 18].

Acceptability and feasibility of the opt-out approach to HIV testing should be thoroughly explored from an HCP perspective before considering a change in testing practice. Diagnostic testing differs from other health interventions because only physicians (or other qualified HCPs) are legally permitted to order and receive financial reimbursement for tests. Fundamentally, every HIV test is the end result of an HCP's decision-making process, which is affected by his or her attitudes, knowledge, experience, and training; and is influenced by colleagues, professional organisations, health systems, and financial incentives. This means that a change in HIV testing practice cannot occur without exploring the attitudes that influence HCPs' decision-making processes. Our aim was to explore HCPs' attitudes toward opt-out HIV testing in an Australian context, to further understanding of its acceptability and feasibility.

Method

Participants

We conducted this qualitative research in Western Australia. Using purposeful and snowball sampling, we recruited participants who were likely to have experience with HIV testing [19]. The sample included primary care nurse practitioners (NPs), general practitioners (GPs), and physician specialists in relevant fields (such as public health) who perform HIV testing in their practice. Among these participants, we chose a variety of ages, settings, and years in practice, to enhance data richness and diversity. We estimated that 20–25 participants would be required to reach data saturation. Between April and November 2014, one researcher (SL) conducted the interviews using a semi-structured guide [see Additional file 1]. Sampling continued until data saturation was reached. This study was approved by the Human Research Ethics Committee at Curtin University. All participants gave written consent to be interviewed.

Data analysis

The interviews were audio-recorded and transcribed verbatim. After transcription we read each transcript several times for data immersion. Using content analysis as described by Graneheim, one researcher (SL) coded the transcripts, which involved placing words or segments of text into categories based on consistency of meaning [20]. Next, the transcripts were independently coded by an experienced qualitative researcher (RM) to enhance the codes' reliability. We then refined the codes through discussion and frequent review of the raw data to find supporting evidence for each code, which was an iterative process that took place over several months [21]. We then combined the codes into subcategories based on similarity of meaning, which we then merged into themes that unified the underlying concepts. We refined these themes through discussion among the research team, and conducted four member checks to confirm theme validity and enhance rigor [22]. We used NVivo software to organise the qualitative data.

Results

We conducted 24 semi-structured interviews. The age of the participants ranged from 31 to 66, with a mean age of 43 years (median = 43; SD = 8.7). Forty-one percent (N = 10) of the participants were female. The mean number of hours per week the participants spent in clinical practice was 28.7 (median = 32.5; SD = 14.8). Seventeen participants were GPs, five were NPs, and two were physician specialists. The number of years since completing general practice or specialty training (or masters' level training for NPs) ranged from one to 43, with a mean of 13.5 years (median = 10, SD = 11.3). Whilst participants were often unsure, the number of estimated HIV tests they had ordered in the previous year ranged from zero to 1000. Similarly, the number of HIV-positive diagnoses participants estimated to have made

over the course of their career ranged from zero to 100. (See Table 1).

We present two findings that emerged from the data. Participants' views about opt-out HIV testing largely fell into two contrasting themes: normalisation and routinisation versus exceptionalism; and a need for proof versus openness to new approaches. Eleven participants had a questioning attitude toward opt-out HIV testing, while eleven favoured the approach. The remaining two participants had more nuanced perspectives that incorporated characteristics of both the questioning and favouring attitudes. See Fig. 1.

Exceptionalism vs normalisation and routinisation

Exceptionalism

Exceptionalism refers to the belief that HIV testing is different from other chronic disease testing [23, 24]. Accordingly, some participants stated that HIV testing was not as relevant, appropriate, or applicable as testing for or preventing other diseases. They saw it as being different from other conditions. One participant explained the clinical decision making process:

> *What's my idea with this patient? I've got to manage the diabetes. Try and get him to stop smoking and prevent cardiovascular disease. Should I test him for HIV? No, probably not.* (Participant 10, GP)

Exceptionalism was sometimes based on the participants' belief that due to patient characteristics or socio-economic status, their patient population was not at risk of HIV. These HCPs felt they were able to profile their patients' behaviour, which was underpinned by assumptions.

> *In the last 12 months, the majority of my practice was one in which the population generally doesn't have at-risk type behaviours–it's an established upper middle class background so it's a relatively low proportion*. (Participant 11, GP)

Other examples of HIV exceptionalism related to pre-test counselling and prevention education, which are not required for other common medical tests.

> *To me the money would be better off increasing the awareness of risk factors rather than spending money on testing every single person. There's no point in testing a nun, for example.* (Participant 21, NP)

Some participants stated that the recent increase in local HIV diagnoses indicated a need for more HIV prevention education, or a need for increased awareness, not a new testing protocol with abbreviated pre-test counselling. Similarly, condensing pre-test counselling would mean that an opportunity to educate people about HIV prevention could be missed.

> *I know that there's a high risk background for many of our clients, there's needle sharing and risk-taking behaviour, but I don't want [opt-out HIV testing] to replace education. The recent HIV statistics show that it's the younger population or heterosexual population, people that are coming back from overseas…I think that's where education has failed rather than [indicating a need to] have everybody tested. If you miss the dialogue then you miss an opportunity.* (Participant 1, GP)

Another aspect of HIV exceptionalism was the concept of stigma. Six participants who expressed discomfort with opt-out testing had beliefs about HIV that suggested they considered an HIV diagnosis a stigma. One participant indicated discomfort with the patient behaviours that led to HIV transmission:

> *And you'd be surprised that plenty* [of patients] *admit to things that you just think, how could they?* (Participant 18, GP)

This discomfort with the sexual and drug use behaviours that could transmit HIV indicated that this participant would not routinely suggest HIV testing during patient consultations.

Table 1 Participant characteristics

Participant characteristic	N (%)	Range
Male	14 (58.3)	
Profession		
GP	17 (70.8)	
NP	5 (20.8)	
Specialty physician	2 (8.3)	
	Mean (SD)	
Age (years)	43.8 (8.7)	31–66
	Median	
Years since specialty training completion	10	1–43
Hours worked per week	32.5	0–42.5
Estimate of HIV tests performed in preceding year	49	0–1000
Estimate of HIV-positive diagnoses during career	N (%)	
Nil	8 (33.2)	
1–5	10 (41.5)	
6–10	2 (8.3)	
>10	4 (16.6)	

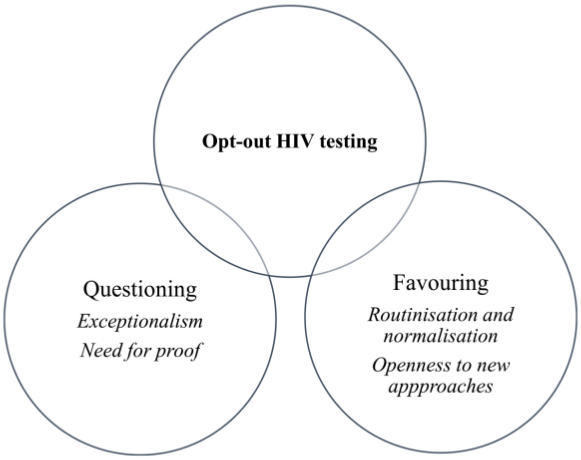

Fig. 1 Concept map of themes

Specialist HCPs frequently mentioned GPs' lack of up-to-date knowledge about HIV epidemiology, possibly related to its historic association with men who have sex with men, a stigmatised group.

> *GP's perceptions on the type of person that has HIV, which are inaccurate considering the large amount of heterosexual transmission in Australia, might not have caught up yet.* (Participant 22, GP)

This suggests that stigmatizing beliefs about HIV prevent GPs from considering testing people from other populations.

Another example of exceptionalism was the concern among some participants that opt-out HIV testing would cause excessive patient anxiety.

> *I don't think it's a good idea to screen almost everyone like that. I don't think that it would be very useful. It might trigger unnecessary anxiety and worries.* (Participant 16, NP)

Two participants mentioned potential for suicide as a possible patient response to an HIV-positive result, causing them to limit HIV testing to special appointments that allowed extra time for patient counselling.

> *It could lead to suicides and so with the anxiety, you're going to need longer appointments for somebody who's coming for HIV testing.* (Participant 12, GP)

Any screening or diagnostic test can cause patient anxiety, but the participants' degree of concern indicated that for them, HIV was unlike testing for other diseases and required special procedures.

Normalisation and routinisation

Normalisation in HIV testing refers to offering testing in the same way for HIV as for as other medical tests for less stigmatised diseases. Despite the relatively low likelihood of finding an HIV-positive result, these participants believed that preventing late diagnosis was a benefit of the opt-out method.

> *Lots of people are going to be negative and* [there would] *be just the odd positive one and you'd probably increase their life span by catching that person, so they're not going to fall in a big heap in ICU with an AIDS-defining illness.* (Participant 7, GP)

Compared with HCPs who tended to question opt-out HIV testing, those favouring it tended to present HIV testing as a normal clinical activity, similar to testing for other chronic conditions (such as diabetes).

> *I just don't see HIV any different to any other long-term disease. Every time I test someone for blood sugar levels I don't go on and on about how awful the disease diabetes is, you know?* (Participant 21, NP)

This participant stated that normalising HIV testing with the opt-out approach could decrease stigma, which could have broader societal benefits.

> *I'm working in a sexual health clinic and essentially I offer it to everybody without taking regard of classic risk factors. We already have a slightly higher risk group and also I just don't think there's any reason not to test for HIV. We're never going to get rid of the stigma around HIV unless we treat it like everything else.* (Participant 7)

Routinisation is similar to normalisation but refers to testing according to a standardised protocol or procedure, as opposed to testing according to clinical indication or risk factor [25]. Opt-out HIV testing would be akin to measuring adult patients' blood pressure at every consult—a routine practice regardless of whether the patient has risk factors for high blood pressure or requests the test. In our study, participants who favoured opt-out HIV testing incorporated it into routine practice, rather than viewing it as an exceptional clinical event. As this participant indicates, making HIV testing a routine part of practice reassures patients that they are not being singled out.

> *It makes it a routine and acceptable thing–the same as we would say, for every pregnant person we always check to make sure you don't have chlamydia, to make sure your blood group, etc., and it normalises it to say there's nothing good, bad or indifferent about being HIV positive. It just means it's better to know than to not.* (Participant 24, specialist physician)

Proof vs openness

Proof

Ten of the 11 participants who had a questioning attitude toward opt-out HIV testing cited a lack of rationale or evidence for a change in testing strategy. In their view, opt-out HIV testing would be reasonable only if there was risk factor-based evidence to support it.

> *I think if there was an evidence base to say, this particular population have x number of risk factors, then* [an] *opt-out test should be offered, then I think that would be completely reasonable.* (Participant 11, GP)

Some referred to evidence-based practice concepts such as statistical significance, pre-test probability, and survival rates, like this participant:

> *I would question the premise of offering HIV testing to everyone. If we're going to offer a group of people a battery of tests, there has to be good evidence that we're going to find that disease in that population. If you can prove that you're going to pick up new infections at a statistically significant rate and prevent adverse outcomes and improve treatment and survival rates, then it's a reasonable thing to do. (*Participant 14, GP)

Some comments indicated a lack of knowledge about the high sensitivity and specificity of current HIV tests, overestimating the risk of a false positive result, such as this GP:

> *I personally would refuse to be tested because I don't want to deal with false positives–it will have some anxiety related to it until you get the results back.* (Participant 18, GP)

This participant did not mention the demonstrated benefits of early HIV diagnosis, and seemed skeptical that knowing one's HIV status could be a positive effect of increased testing.

> *I'd like to see the evidence first* [about] *the benefit, that every single person in the country knows their HIV status. If we tested every single person for HIV, I'd like to know how many more people we are picking up that we're missing. I'd like to know if early diagnosis reduces complications afterwards. (*Participant 21, NP)

Need for proof was often framed in terms of cost-effectiveness. Participants stated that if HIV testing were increased, more beneficial health interventions could be neglected.

> *You'd need to look at whether or not the number of new diagnoses you made is worth the cost or whether your portion of health money could go into something else that would be potentially more valuable.* (Participant 3, GP)

Need for proof was also associated with a fear of reprimand. Participants indicated that if they performed more HIV tests, Australian government funding bodies (Medicare) would question its appropriateness.

> *Medicare would be tapping on my door asking why I'm doing so many HIV tests, and can I justify the expense to the government?* (Participant 24, GP)

The need for proof of concept was seen as important to protect HCPs delivering what they perceived to be potentially contentious care.

Openness to new approaches

Openness to new testing approaches was a common attitude among participants who favoured opt-out HIV testing. Participants often referred to the benefits of increased HIV testing and mentioned positive outcomes from other countries. One participant stated that opt-out testing could prompt HCPs to test more patients for HIV.

> *So, I think it's a good thing to have and it just makes us think about us doing it more as opposed to thinking about doing it less.* (Participant 6, NP)

This participant was aware of evidence about opt-out HIV testing from other countries and considered its implications for her practice:

> *I think that it's being shown in countries like England around the pregnancy testing and I think it is dangerous when people do their own risk assessment. And what they found in England is that obstetricians got it wrong.* (Participant 23, GP)

Unlike the HCPs who had a more questioning attitude toward opt-out HIV testing, participants who were open to the approach thought that the cost of opt-out HIV testing was reasonable and would be acceptable to the public.

> *To me it seems a well-run, well-managed process…it's not a massive cost on the public purse that people get agitated about.* (Participant 8, GP)

This participant advocated expanding opt-out testing to the emergency department to expand access to HIV testing:

> *You could do it in EDs, you could do it in other settings where there's a much bigger throughput.* [ED] *might not be a bad spot to target because they're seeing a cross sections of people that wouldn't usually access health services.* (Participant 7, GP)

Discussion

This initial study of Australian HCPs' views on opt-out HIV testing revealed new insights and some surprise findings. The majority of participants' views fell into one of two mutually exclusive categories: favouring or questioning. Participants who tended to question opt-out HIV testing doubted its relevance to Australia, focused on the method's flaws, and emphasised potentially negative consequences. Surprisingly, they did not identify some of the barriers to opt-out HIV testing that commonly appeared in previous research, such as operational issues [15, 26, 27], time constraints [28–30] or inadequate linkage to HIV care [31]. Conversely, participants who were generally comfortable with opt-out HIV testing had similar views to those identified in previous research, such as placing HIV testing in the same domain as testing for other diseases [27, 31]. Finally, pilot studies provide useful data about changes in clinical practice before wider implementation, but participants in this study did not suggest a pilot test of opt-out HIV testing in an Australian setting.

Participants who had a questioning attitude toward opt-out HIV testing doubted its relevance to the general Australian population, citing a lack of evidence for efficacy in lower prevalence populations. Australia has a low HIV prevalence by global standards; however, the idea that HIV testing is irrelevant in areas with low rates of infection has been considered the "false security" of low prevalence [29] (p.75), potentially resulting in delayed HIV diagnosis. Participants in this category stated they were able to accurately determine which patients should be tested based on their characteristics (such as age or suburb of residence), a strategy that previous studies have shown to be ineffective in identifying HIV infections [5, 32–34]. Opt-out HIV testing could decrease the potential for error in patient risk assessment.

Participants who questioned the opt-out approach to HIV testing tended to focus on its potential flaws, which may reflect HCPs' analytical style [35–39]. While HCPs are trained to look for logical negatives (for instance, they might ask themselves, "what is wrong with this picture?" in the diagnostic process), this frame of mind could lead to pessimism about changes in practice [40]. Studies have shown that HCPs are particularly reluctant to change their practice in view of new evidence [35] and are prone to "paralysis by analysis"—which occurs when the discussion about a change becomes so arduous that no action is taken [41]. Our data also suggest that HCPs sometimes make decisions about HIV testing based on personal beliefs and values, not necessarily logical reasoning, which is consistent with behavioural economic theory [42]. A change in HIV testing practice should take into account these common HCP analytical patterns. A small, incremental trial should provide feasibility data that could be used to determine the efficacy of opt-out HIV testing, without 'forcing' HCPs into a major change too quickly [43].

Some HCPs seemed to need more support and education about HIV testing and disclosure of results. Participants who viewed opt-out HIV testing less favourably were worried about potential negative consequences, such as stigma, anxiety and suicide, supporting previous research findings [29, 31, 44, 45]. Studies have shown that HCP education can facilitate implementation of opt-out HIV testing (which would be especially important in Australia, given that many participants in this study had limited knowledge of, or experience with, the

approach) [46]. Academic detailing (brief, one-on-one education sessions) prior to large-scale implementation of opt-out HIV testing has been shown to increase its acceptance among HCPs [47]. Peer-based education could be particularly effective because it provides a social reference for HCPs (who are often unconsciously influenced by their peers) [48, 49]. Because many participants in our study were worried about disclosing HIV-positive results, HCPs should receive education about best practices for disclosure, ideally with a protocol for linkage to HIV care already in place [14, 45, 50]. Education programs have also been shown to promote positive HCP attitudes toward opt-out HIV testing, with HCPs citing patient behaviour change and reduced HIV transmission as affirming aspects of the approach [31, 51].

Although they tended to disapprove of opt-out HIV testing for the general Australian population, participants who had a questioning attitude had flexible beliefs: they were not necessarily opposed to opt-out HIV testing, provided there was Australian evidence of efficacy and cost-effectiveness. They were willing to revise their attitudes based on new information or experience, which has been associated with increased acceptance of opt-out HIV testing [32]. Research about opt-out HIV testing has shown that ongoing quality improvement activities (particularly with HCP participation) are essential for making changes in practice [52]. Similarly, knowledge translation studies have demonstrated the importance of short-term, small-scale pilot tests before expanding new programs [53]. Surprisingly, regardless of whether they were comfortable with opt-out HIV testing, participants in this study did not suggest short-term trials or small-scale quality improvement projects before considering broader implementation.

Few participants who were comfortable with opt-out HIV testing mentioned its cost, indicating that for them, potential benefits of the approach outweighed the costs. There is scant international evidence about HCP views on the cost of opt-out HIV testing. Further, most studies on opt-out HIV testing were conducted in the US and funded by federal grants, which may account for the lack of cost concerns among US participants [53]. Future research should explore HCP attitudes about the cost of opt-out HIV testing and their effects on changes in testing practice.

This study has provided an initial insight into the acceptability of opt-out HIV testing in Australia. While some HCPs have embraced the opt-out approach, risk factor-based HIV testing remained entrenched among some participants. Subsequent research could best inform future HIV testing recommendations by addressing the issues raised by the HCPs who viewed opt-out HIV testing less positively [54]. Given some participants' concerns about over-testing and excessive cost, existing Australian cost-effectiveness modelling data should be more widely disseminated and replicated [55]. Efficacy and feasibility data about opt-out HIV testing through a pilot study in an Australian context could meet HCPs' need for evidence [32]. Finally, Australian research on opt-out HIV testing should explore the operational barriers (such as time constraints) identified in international research.

Methodological considerations

Our results should be interpreted within their methodological context. The interviews were conducted by a clinician-researcher (SL) who had experience with opt-out HIV testing in the US (where the opt-out approach has been recommended for nearly a decade). During the interviews, the participants sometimes asked the researcher questions about opt-out HIV testing in the US, which was a diversion from the aim of the research, and may have influenced their views (but also supported their need for education). Although we actively recruited participants with negative or differing opinions about opt-out HIV testing, the sampling method may have resulted in a limited spectrum of perspectives. Due to the small sample size, we were not able to make separate subgroup analyses within the sample, such as a comparison of attitudes between HCPs with different levels of experience. Another limitation was that the participants practiced in one Australian state, which may not represent the full range of Australian HCPs' views.

Conclusion

Most HCPs in this study had dichotomous attitudes toward opt-out HIV testing, reflecting contrasting analytical styles. While some HCPs viewed it favourably, with the perceived benefits outweighing the perceived costs, others preferred to have evidence of efficacy and cost-effectiveness. In response to the findings from this study, we have designed a pilot test of opt-out HIV testing in an Australian general practice. The pilot test will explore HCP and patient experiences with the opt-out approach, compare the number of HIV tests and results between opt-out and traditional testing, and analyse the cost impact of opt-out testing. Findings from this pilot test should help to inform the desirability of introducing opt-out HIV testing in Australia.

Additional file

Additional file 1: Interview guide. (DOCX 16 kb)

Competing interests

The authors declare that they have no competing interests.

Authors' contributions
SL: Conceived and designed the research, conducted interviews, analysed data, and wrote the manuscript. RM: Conceived and designed the research, analysed data, and revised the manuscript. DB: Conceived and designed the research, analysed data, and revised the manuscript. SW: Revised the manuscript. SG: Conceived and designed the research, analysed data, and revised the manuscript. All authors have read and approved the final manuscript.

Acknowledgements
SL is an Australian Postgraduate Award recipient. We thank the HCPs who took part in the interviews. We also thank Homeless Health and the Royal Perth Hospital Department of Clinical Immunology for assistance with recruitment.

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Received: 21 May 2015 Accepted: 4 September 2015
Published online: 14 September 2015

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CHAPTER 4

THEORETICAL CONSIDERATIONS

Theoretical analysis is further explored in the following publication, Leidel, S., Leslie, G., Boldy, D., & Girdler, S. (2016). A comprehensive theoretical framework for the implementation and evaluation of opt-out HIV testing. *Journal of Evaluation in Clinical Practice, http://dx.doi.org/10.1111/jep.12602*. In this publication, three theories are combined to explore and synthesise aspects of opt-out HIV testing, from health care provider beliefs (the Health Belief Model) to the benefits of defaults in health care (Behavioural Economics), and finally to the operational processes required for implementation into practice (Normalisation Process Theory). This theoretical framework in the following article was used as the coding scheme for the qualitative data in the final phase of this research.

Article 4. A comprehensive theoretical framework for the implementation and evaluation of opt-out HIV testing.

Journal of Evaluation in Clinical Practice
International Journal of Public Health Policy and Health Services Research

Journal of Evaluation in Clinical Practice ISSN1365-2753

A comprehensive theoretical framework for the implementation and evaluation of opt-out HIV testing

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Keywords
epistemology, healthcare, public health

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Accepted for publication: 16 June 2016

doi:10.1111/jep.12602

Abstract

Opt-out HIV testing (in which patients are offered HIV testing as a default) is a potentially powerful strategy for increasing the number of people who know their HIV status and thus limiting viral transmission. Like any change in clinical practice, implementation of opt-out HIV testing in a health service requires a change management strategy, which should have theoretical support. This paper considers the application of three theories to the implementation and evaluation of an opt-out HIV testing programme: Behavioural Economics, the Health Belief Model and Normalisation Process Theory. An awareness, understanding and integration of these theories may motivate health care providers to order HIV tests that they may not routinely order, influence their beliefs about who should be tested for HIV and inform the operational aspects of opt-out HIV testing. Ongoing process evaluation of opt-out HIV testing programmes (based on these theories) will help to achieve individual health care provider self-efficacy and group collective action, thereby improving testing rates and health outcomes.

Introduction

In opt-out HIV testing, health care providers present HIV testing to patients as a default option (e.g., 'we are going to test you for HIV unless you decline') [1]. This approach differs from traditional HIV testing, which is performed according to a patient's risk factors for the infection. Opt-out HIV testing is a potentially powerful strategy for increasing the number of people who know their HIV status and limiting viral transmission [2,3]. The agenda for a change to opt-out HIV testing became widely known in 2006, when the US Centers for Disease Control issued a recommendation to perform opt-out HIV testing for the general population between the ages of 13 and 64 [1]. Since 2006, other health organisations have issued similar guidelines [4,5] and the practice has expanded to some countries outside the USA, such as the UK [6]. Since 2007, the World Health Organisation has advised that opt-out HIV testing should be considered in a variety of health settings, particularly in areas with generalized HIV epidemics, which has been re-iterated in its 2015 guidelines [7,8]. Research evaluating opt-out HIV testing has found that it has a positive impact on health outcomes and is generally acceptable to both patients and health care providers across a variety of health care settings [2,9,10]. However, researchers have also reported barriers to full implementation, such as ethical concerns among staff performing HIV testing [11], patients perceiving themselves to not be at risk [12,13], and provider discomfort with testing and giving results [14]. A theory-based strategy could be useful in addressing these barriers.

Opt-out HIV testing could be a valuable strategy for health services that aim to improve quality through the implementation of evidence-based guidelines. Like any change in clinical practice, successful implementation of opt-out HIV testing in a health service requires a change management plan. Theoretical constructs have become increasingly recognized as an important part of implementing practice changes [15,16]; they not only enhance the development of the change in practice, but also describe elements of the process that can be objectively evaluated after implementation [17,18]. Theories that emphasize distinct elements of the change process (such as a health care provider's decision-making processes, beliefs and ability to operationalize new practices) can be integrated into an implementation strategy and process evaluation for novel practice concepts such as opt-out HIV testing. This paper will consider the application of three theories, which can be broadly applied to the implementation and evaluation of an opt-out HIV testing programme: Behavioural Economics, which was chosen because of its emphasis on use of defaults to promote behaviour change and support decision-making processes [19]; the Health Belief Model, which was chosen for its perspective on the beliefs that underlie health behaviour change (which in turn enhances practice change) [20]; and Normalisation Process Theory, which addresses health system changes and facilitates new practices on an operational level [21]. Refer to Table 1.

Behavioural economics

The implementation and evaluation of an opt-out HIV testing programme can be enhanced by integrating behavioural science

Table 1 Selected key interventions that were successfully implemented using Behavioural Economics, the Health Belief Model and Normalisation Process Theory.

Theory	Intervention that was successfully implemented using the theory
Behavioural Economics	
Probst *et al.* (2013) [34]	Physicians in a US paediatric hospital were more likely to order recommended blood tests when the tests were presented as defaults in the electronic health record.
Shaikh *et al.* (2015) [71]	Opt-out testing was superior (compared with an opt-in method) at finding chlamydia cases in a US correctional facility.
Abadie *et al.* (2006) [28]	Countries with an opt-out system of organ donation (in which being an organ donor is the default) have higher transplantation rates than countries with opt-in organ donation.
Cohen *et al.* (2005) [35]	Pre-stamped laboratory forms for opt-out blood tests were effective at increasing testing rates and identifying new syphilis infections.
Health Belief Model	
Lenz (2008) [39]	Student nurses who were smokers were less likely than non-smokers to believe that it was their role to help their patients quit smoking or to support tobacco control interventions.
Grubbs (2000) [40]	Recommendations to use sunscreen were more likely when health care providers' perceived susceptibility of their patients' skin cancer risk was accurate.
Buckelew (2008) [43]	Role-play-based training for health care providers increased their self-efficacy in counselling adolescents about risky behaviours.
Normalisation Process Theory	
Drew (2015) [56]	Fracture prevention coordinators, use of patient databases and multi-disciplinary planning meetings facilitated an Normalisation Process Theory-based hip fracture prevention programme in the UK.
Leon (2013) [57]	Nurses in an opt-out testing programme in South Africa continued with the programme despite barriers.
Bamford (2012) [55]	Normalisation Process Theory was used to implement nutrition guidelines (and solve problems with implementation such as lack of collective action) in UK residential care homes.

principles into the change strategy. As an amalgam of economics and psychology, behavioural economics explains how health care providers can be influenced to offer HIV testing [22,23] (Fig. 1). Behavioural Economics offers a more pragmatic view of decision making than classical economic theory (which posits that health care providers make sound, unbiased choices about testing their patients for HIV) [24,25]. Ideas from behavioural economics are increasingly used by governments in the design of health programmes [26–28], but are less commonly applied to individual provider–patient encounters. In the case of HIV testing, despite the plethora of evidence-based guidelines that advocate the opt-out approach, opportunities to test are still being missed [3,29,30]. By aligning a change strategy with principles from Behavioural Economics, health care providers can be 'nudged' to adopt opt-out HIV testing [31].

'Choice architecture' refers to the way health care providers present HIV testing to their patients [19]. For example, telling a patient 'We do HIV tests on everybody unless they do not want to be tested…' is an example of framing the HIV test as a normal activity, which could reassure a patient that he or she is not being 'singled out' for testing. Health care providers can use framing to emphasize positive aspects of knowing one's HIV status and to

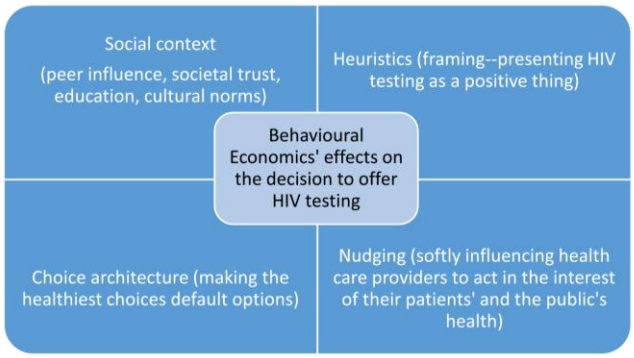

Figure 1 Behavioural economics and opt-out HIV testing.

educate patients that HIV treatment is a manageable chronic condition, thereby 'nudging' them to be tested [32].

Choice architecture can be designed to make HIV testing a part of routine clinical practice. Defaults influence health care provider behaviour by reducing medical uncertainty: because all patients are tested for HIV, health care providers do not have to assess their patients' risk or decide who should be tested and who should not. Default reminders can also keep health care providers from overlooking recommended tests [33,34]. HIV testing could easily be added onto orders for other laboratory tests that are often done on a default basis (such as cholesterol screening). One study showed that pre-stamped laboratory forms for opt-out blood tests are effective at increasing testing rates and identifying new infections [35]. These defaults make it more likely that health care providers would order recommended HIV tests [36].

The Health Belief Model

Health care providers' beliefs about their patients' susceptibility to health conditions have been shown to affect their practices [37–40]. Beliefs also influence how strongly health care providers encourage their patients to be tested for many conditions, including HIV [41]. The Health Belief Model is a theoretical framework that was originally developed to understand patients' capacity to make health-related behaviour changes [20,42]. Although this model is most recognized for its application to patient health promotion, studies suggest that the Health Belief Model can also be applied to health care provider behaviours related to patient care [43]. The model is comprised of five constructs that should be integrated into the implementation and evaluation of an alternative approach to health practice such as opt-out HIV testing programme (Fig. 2).

Implementation of opt-out HIV testing requires health care provider self-efficacy, which is the effort to change practice and persist with the change despite barriers [44]. As implementation progresses, health care providers usually gain confidence that they can manage the operational aspects of a change in practice such as opt-out HIV testing (giving test results, providing education and making referrals if necessary). When they overcome adverse experiences or barriers to the change in practice, self-efficacy is enhanced further [44]. Improved patient outcomes from opt-out HIV testing lead to more enthusiasm for the change and a determination to continue with it [45]. Because of its potentially positive influence on persistence through adverse events, self-efficacy should be assessed in the process evaluation of practice changes such as opt-out HIV testing programmes.

In Fig. 2, 'perceived susceptibility' refers to health care providers' beliefs about the likelihood that their patients will get a disease [42]. For example, some HCPs believe that they are able to select patients for HIV testing based on demographic information [46]. Even though there is a low prevalence of HIV in Australia, the ability to select patients for testing is lacking. An Australian study found that even in a sexual health setting (where HIV testing would be relatively more common than in general practice), patients were seen several times in the year before their HIV diagnoses, indicating that the health care providers did not initially perceive them to be susceptible to the infection [30].

'Perceived severity' is a health care provider's belief about the seriousness of a health condition [42]. HIV has always been considered a serious disease, and in the early years of the epidemic, being HIV positive was considered to be a death sentence [47]. Now that HIV is a chronic, manageable condition (at least in areas with specialized HIV care), finding people with undiagnosed HIV at an early stage so they can access appropriate anti-retroviral treatment is vital to patient and community wellbeing [35,48]. Opt-out HIV testing may trigger a referral that a patient would not have initiated him or herself [14,36].

'Perceived benefits' are the potential positive effects of opt-out HIV testing that could influence health care providers to adopt the practice if integrated into any implementation strategy [49]. These benefits occur at three levels: (1) getting an early diagnosis; (2) once detected, HCPs feel rewarded when they can refer; and (3) once referred, the risk of transmission is reduced, which benefits public health. A qualitative study found that health care providers participating in an opt-out HIV testing programme felt especially rewarded when they were able to refer HIV-positive patients to specialty care at the time of diagnosis. With traditional HIV testing, these patients may not have known their HIV status, denying them access to early treatment and an opportunity to make lifestyle changes that enhance their own health and reduce the risk of transmission to others [14].

'Perceived barriers' are health care providers' negative beliefs about opt-out HIV testing that could limit their willingness to adopt such an approach. For example, health care providers may assume that their patients are unwilling to be tested for HIV or that testing would lead to anxiety or stigma [46]. Some health care

	Perceived susceptibility	Perceived severity	Perceived benefits	Perceived barriers	Cues to action	Self-efficacy
Definition	How likely it is to affect a given individual?	How serious is the risk from the disease?	What negative consequences can be avoided and what positive consequences can be maximised?	What costs, losses, or disadvantages result?	Reminders, motivators, or hints that increase the likelihood of behaviour change.	The person's confidence and ability to accomplish the behaviour change.
In context of opt-out HIV testing	The likelihood of having a patient test positive for HIV.	HCP beliefs about the severity of HIV and triggers for referral.	Timely linkage to HIV care, undetectable viral load, and decreased viral transmission.	Inadequate time, resources; competing priorities; stigma/discrimination; or HIV-positive patients not linked to specialty care.	Electronic medical record reminders, peer influence (one-on-one or via social networks).	HCPs' confidence in applying the opt-out method and making referrals if needed

Figure 2 The Health Belief Model and opt-out HIV testing.

providers may be concerned when opt-out HIV testing is performed with abbreviated pre-test counselling and simplified consent [50]. Health services should minimize these concerns through education and peer encouragement during the implementation phase, while ensuring that barriers continue to be examined and mitigated during the evaluation phase.

'Cues to action' are factors that influence health care providers to initiate a test or treatment such as HIV testing, for example, computer reminders in medical record software, standing orders for nursing staff, education sessions about the benefits of opt-out HIV testing or peer influence [51,52]. By planting cues to action, academic detailing (peer-to-peer education) has been shown to increase health care providers' guideline knowledge and potentially influence their adoption of opt-out HIV testing [53]. Peer influence is an effective way to engage health care providers with a practice change and enhance their self-efficacy [54].

Normalisation process theory

While Behavioural Economics and the Health Belief Model form a basis for understanding individual health care providers' decision-making habits and health beliefs, Normalisation Process Theory offers a group-oriented, action-based structure for integrating practice change (such as opt-out HIV testing) into a health service's day to day operations [10] (Fig. 3). It has been used in a variety of health interventions, including a trial of opt-out HIV testing in South Africa [55–57]. Implementation of opt-out HIV testing into existing clinical workflows can be complex, and health care providers often resist change from the status quo [58]. Normalisation Process Theory addresses this complexity by bridging social science with health care in a way that considers both human agency (the ability to make changes in health care practice) and the social context of the health service (the collective action of a team of health care providers toward a common goal) [17]. The goal of Normalisation Process Theory is to implement a new practice so that it becomes permanently embedded in a health service's day-to-day procedures, and is now a major component of a general implementation theory for health innovations [17]

In Fig. 3, 'coherence' refers to the ways in which health care providers (both as individuals and as members of clinical teams) operationalize new concepts in their practice [59]. For example, health care providers who have never reflected on different approaches to HIV testing, or who do not see any value in the opt-out approach, would be considered to have *low coherence* [60]. Peer influence can make health care providers more likely to adopt opt-out HIV testing by raising their *level of coherence* [61]. Implementation efforts should include academic detailing about the advantages of opt-out HIV testing for both individuals and the public [53].

'Cognitive participation' is the collective integration of new practices into a health service's existing workflow, based on iterative processes of team or workflow organisation and re-organisation. For example, if nurses have to perform the HIV test separate to other tests, use a different blood collection tube, fill out another form or take the patient to another area, the usual workflow is disrupted, making the change potentially unsustainable. Workflows should be dynamic and responsive to health care providers' needs and contributions, to enhance their commitment to the project [59].

'Collective action' refers to health care providers' confidence that they can work with their colleagues to carry out the change from risk factor-based HIV testing to the opt-out approach [59]. This shared commitment is different from a common scenario in which the management team institutes a change from the 'top down'. In Normalisation Process Theory, all members of the team participate in implementing the change and eventually attain accountability for the change [62].

'Reflexive monitoring' is the process of evaluating a practice change, such as analysing adverse events or examining factors that affected health care provider and patient uptake of a change process like opt-out HIV testing [21]. In this phase, both individuals and teams of health care providers assess the overall value of the practice change, such as whether it was excessively disruptive to the workflow, unacceptable to patients or overly time-consuming. This evaluation step allows health care providers to consider ways to improve the coherence of opt-out HIV testing (such as providing feedback to nurses about the increased number of HIV tests

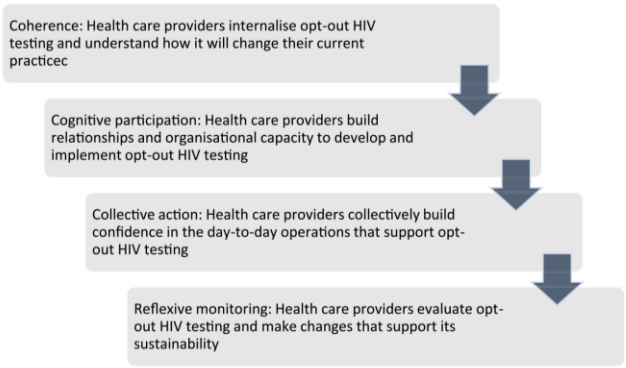

Figure 3 Normalisation Process Theory.

or HIV-positive patients referred for specialized HIV care) [63]. Reports that compare providers' performance with each other (as opposed to an audit-feedback approach) have been shown to be particularly effective in 'nudging' them to adopt evidence-based practices [61,64,65].

Discussion

The science of implementing evidence-based practice changes into clinical practice continues to evolve and is increasingly built upon theoretical concepts, but these theories are rarely brought together as a unified entity. The problem for health services trying to implement new practices is deciding which theory to use among the abundant choices. Because there is no one universal theory that explains every aspect of implementation, adoption and evaluation, a holistic approach to theory can enhance real-world feasibility. Amalgamating theoretical models can provide a well-rounded, wide-ranging structure for successful practice change in the case of opt-out HIV testing (Fig. 4).

Constructs from Behavioural Economics, the Health Belief Model and Normalisation Process Theory overlap in ways that can make the implementation process more salient to health care providers while providing an all-inclusive structure for evaluation. Figure 4 shows the constructs with common characteristics, such as *cues to action* (from the Health Belief Model) and *default options* (from Behavioural Economics) that can be brought together for implementation and evaluation of challenging practice developments like opt-out HIV testing. *Self-efficacy* and *collective action* represent the central constructs shared across the three theories, or the point of model convergence.

The ultimate goal for implementing opt-out HIV testing is for the individual health care providers to achieve *self-efficacy* (from the Health Belief Model) and for the health care team to achieve *collective action* (from Normalisation Process Theory). Health

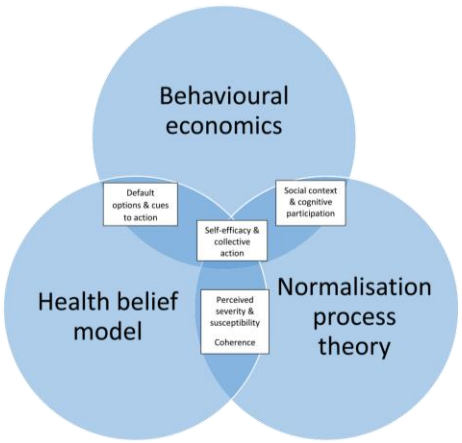

Figure 4 Integration of theories for the implementation and evaluation of opt-out HIV testing.

care providers display a high degree of conformity [53,66] and a steadfast respect for each other's autonomy, both of which run counter to the shared commitment required for implementing new practices [54,67]. Health care providers may disagree about the need for a particular test or intervention, yet combining constructs from Behavioural Economics (nudging with defaults) and Normalisation Process Theory (improving coherence) may lead to greater agreement about the need for opt-out HIV testing [55,68].

The basis for linking concepts from Behavioural Economics, the Health Belief Model and Normalisation Process Theory is a dynamic one. For instance, the concept of coherence from Normalisation Process Theory is directly related to perceived severity and susceptibility from the Health Belief Model. Health care providers' coherence with respect to opt-out HIV testing depends on their belief that HIV is serious and that their patients are vulnerable to it. Interventions in the development and implementation phases should maximize coherence and boost perceptions of susceptibility. Once implementation begins, health care providers should be asked to appraise coherence and perceived susceptibility, because these constructs may change over time (for example, if a low-risk patient has an HIV-positive result, perceived susceptibility and coherence would increase).

Another advantage of applying more than one theoretical approach to changes in practice is that constructs from one theory can supplement and support others. For example, the Health Belief Model emphasizes individual health care provider beliefs, while Normalisation Process Theory relates to the actions of an entire workgroup of providers. And while Behavioural Economics and the Health Belief Model explain health care provider behaviours and beliefs, these concepts relate more to the implementation phase than to the evaluation, which is no less important. Reflexive monitoring from Normalisation Process Theory is the only construct that provides a way to determine the value of opt-out HIV testing, an essential aspect of successful health care innovation.

Merging Behavioural Economics, the Health Belief Model and Normalisation Process Theory creates a structure for an opt-out HIV testing programme that is broader than the individual theories alone, but the combination still has limitations. We have proposed a simple example (based on health care provider beliefs and decision making) that may be better placed in complex interventions. Normalisation Process Theory in particular is directed at broad, multifaceted changes in practice [21,69].

A weakness of the theories is their lack of emphasis on shared decision making with patients. By focusing on health care providers' decision making, beliefs and ability to carry out opt-out HIV testing, the theories assume that patients will be accepting of the practices their providers promote. Shared decision making between health care providers and patients is an increasingly important area in health research and policy, and may be a vital part of process evaluation in the future [70]. Whenever possible, implementation and evaluation of any care (but in particular approaches such as opt-out HIV testing) should occur in collaboration with patients.

Conclusion

This paper has considered three theories that form a holistic implementation and evaluation plan for an opt-out HIV testing

programme. Constructs from Behavioural Economics, the Health Belief Model, and Normalisation Process Theory complement and reinforce each other in a more powerful way than the individual models could. This fusion of theories 'nudges' health care providers to order tests that they may not routinely order, influences their beliefs about who should be tested for HIV and informs the operational aspects of opt-out HIV testing. Ongoing process evaluation of health practice changes (in this case opt-out HIV testing programmes) based on these theories will help to achieve individual health care provider self-efficacy and group collective action, thereby improving health decision actions (such as testing rates) and ultimately health outcomes.

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CHAPTER 5

MIXED-METHODS STUDY

Current HIV treatment guidelines recommend that all people with HIV take anti-retroviral medications from the time of diagnosis to improve long term health outcomes (Australasian Society for HIV Medicine, 2017). People diagnosed outside of a specialty HIV service should be referred immediately to an HIV treatment program to start these medications. This process of connecting HIV-positive individuals to HIV treatment services is called linkage to care. The World Health Organization defines linkage as: "the period beginning with HIV diagnosis and ending with enrolment in care or treatment" (World Health Organization, 2015)p.32). The current international goal is for 90% of people newly diagnosed with HIV to be linked to care (UNAIDS, 2014).

If HIV treatment services are limited, or treatment is available but patients do not establish care with HIV services, they do not benefit from early initiation of anti-retroviral medications. Treatment services typically provide patient counselling about avoiding transmission to others, which has been shown to benefit public health. Without established links to HIV treatment services, HIV testing programs confer no benefit to the patient's or the public's health (Branson et al., 2006; World Health Organization, 2015). Due to the lack of benefit of testing without referral for antiretroviral medications, the World Health Organization recommends HIV testing only in areas where HIV treatment is available.

Australia's Seventh National HIV strategy also recommends that newly diagnosed patients with HIV are promptly referred for treatment (Australian Government Department of Health and Ageing, 2014). Up to 50% of people living with HIV in Australia are not receiving HIV treatment because they were not connected to care or not retained in care (Wilson & Henderson, 2015).To increase the number of HIV-positive people who are engaged in treatment, barriers to care like access to specialty services, access to pharmacies that dispense antiretroviral medications, and lack of transportation should be addressed (Australian Government Department of Health and Ageing, 2014).

Ethical issues

The ethical basis for opt-out HIV testing includes confidentiality, informed consent, and linkage to care (Johnson, 2007). In the final study in this thesis, health care providers at Homeless Healthcare adhered to their usual practices around confidentiality. For example,

patients discussed HIV testing and had their blood drawn in a private exam room. Only clinical staff with direct care responsibilities were present, and providers did not divulge any patient information to staff not involved with that patient or other patients. Test results were not given over the phone or left on voice mail. Patients were asked to return for a follow-up visit to discuss their results. If a patient was found to be HIV-positive, the HIV treatment service was notified directly by health care providers not office staff. Results were reported to the Health Department without patient-identifying information (Western Australia permits anonymous reporting of HIV).

Health care providers who perform opt-out HIV testing have an ethical duty to obtain consent prior to testing, ensuring that patients are tested on a voluntary basis. In the final study in this thesis, the participating health care providers obtained consent first with the general consent for medical treatment and then prior to performing opt-out HIV testing. Linkage to care is an additional ethical responsibility for providers who conduct opt-out HIV testing and is discussed below.

Linkage to care in the present research

The importance of linkage to HIV care as described above was integrated into the design of the final study in this thesis: a prospective, mixed-methods trial of opt-out HIV testing at Homeless Healthcare, a primary health care practice in Perth, Western Australia. This study aimed to determine if the opt-out approach affected HIV testing rates and explored its acceptability among health care providers. It was possible that previously undiagnosed HIV infections might be discovered during the study period. The study was designed with a mechanism for connecting newly diagnosed HIV-positive individuals with HIV specialty care. Ethical issues around HIV testing were considered in the design of the trial because HIV infection is a stigmatized condition. Over the past few years, researchers and clinicians have developed a model called the HIV care cascade (Kay, Batey, & Mugavero, 2016).

In metropolitan Perth, HIV treatment services are delivered by the departments of clinical immunology at Royal Perth and Fremantle hospitals. When a patient tests positive for HIV, the provider who ordered the test is notified of the result by the laboratory. The provider then contacts the patient to discuss the results and refer him or her to one of the treatment clinics. In the present study, it was essential to ensure that this connection was formalized because opt-out HIV testing program may uncover new diagnoses in people who are asymptomatic.

The remaining research objectives relate to the trial of opt-out HIV testing at Homeless Healthcare, which is presented in this chapter as a publication: Leidel, S., Leslie,

G., Boldy, D., & Girdler, S. (2017). "We didn't have to dance around it:" opt-out HIV testing among homeless and marginalised patients. *Australian Journal of Primary Health.* The objectives were to design and trial an opt-out model of HIV testing in a primary health care setting, examine health care providers' perceptions of the change, and determine if the pilot test increased HIV testing rates. Finally, the trial aimed to evaluate the acceptability and feasibility of opt-out HIV testing for health care providers.

Reflexivity

The author of this thesis was employed as a nurse practitioner at Homeless Healthcare before and during data collection and analysis. Her experience with opt-out HIV testing and in-depth knowledge of its related issues could have influenced her peers' attitudes or testing practices. To avoid introducing bias, the author was not a participant in the research and did not discuss opt-out HIV testing with participants during the study period. The number of HIV tests she conducted during the study period was not included in the data.

Methodological approach and data analysis

The following study is a small-scale trial of opt-out HIV testing in a single health service, corresponding to the initial implementation phase of the Implementation Science conceptual framework. A mixed-methods design was chosen to interpret the opt-out HIV testing data together with the health care providers' experiences. Combining the two data types would best inform development of a plan for wider implementation.

This study took a novel approach to qualitative research by using a previously developed theoretical framework to conduct interviews and code and analyse the data. This process shared some characteristics with framework analysis, a qualitative method similar to grounded theory. Framework analysis is useful when the research aims to describe a specific group (like the health care providers at Homeless Healthcare), and typically leads to straightforward descriptions and interpretations of phenomena (Ritchie & Spencer, 1994). A more traditional approach to data analysis (e.g., grounded theory) could have identified different themes or generated a new theory.

Ethics approval

This final study was approved by the Human Research Ethics Committee of Curtin University. Homeless Healthcare did not have an ethics committee, so the principal investigator presented the research proposal to a meeting that included the medical director and board of directors. This group agreed to participate in the research and provided a letter of support.

Article 5. “We didn’t have to dance around it:” opt-out HIV testing among homeless and marginalised patients.

CSIRO PUBLISHING
Australian Journal of Primary Health
http://dx.doi.org/10.1071/PY16120
Research

‘We didn’t have to dance around it’: opt-out HIV testing among homeless and marginalised patients

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Abstract. This study explored opt-out HIV testing in an Australian general practice. The aims were to: (1) determine the effect of the opt-out approach on the number of HIV tests performed; and (2) explore the acceptability of opt-out HIV testing from the healthcare providers’ perspective. A prospective mixed-methods study of opt-out HIV testing over a 2-year period (March 2014–March 2016) was conducted. Implementation was based on a theoretical framework that was developed specifically for this study. The setting was Homeless Healthcare, a health service in Perth, Western Australia. The number of HIV tests conducted during the control year (usual practice) was compared with the intervention year (opt-out testing). After the intervention, the healthcare providers ($n = 8$) were interviewed about their experiences with opt-out HIV testing. Directed content analysis was used to explore the qualitative data. HIV testing rates were low during both the control year and the intervention year (315 HIV tests (12% of the patient cohort) and 344 HIV tests (10%) respectively). Opt-out HIV testing was feasible and acceptable to the participating healthcare providers. Other health services could consider opt-out HIV testing for their patients to identify people with undiagnosed infections and sustain Australia’s low HIV prevalence.

Additional keyword: Australia.

Received 28 September 2016, accepted 3 February 2017, published online 20 April 2017

Introduction

In opt-out HIV testing, healthcare providers inform patients that they are going to be tested for HIV unless they decline or defer (Branson *et al*. 2006). Over the past decade, opt-out HIV testing has become routine in some countries (Viall *et al*. 2011) and is recommended for pregnant women in Australia (Royal Australian and New Zealand College of Obstetricians and Gynaecologists 2015). Research from the United States, the United Kingdom, Spain and other countries has shown that opt-out testing is feasible and acceptable to both patients and healthcare providers (Bath *et al.* 2015; Navaza *et al*. 2016). Although Australia has been recognised for its leadership in HIV prevention, to our knowledge, opt-out HIV testing has never been explored in Australian general practice. Our previous study of Australian healthcare providers’ views on opt-out HIV testing found that half of the participating GPs questioned the acceptability and feasibility of the approach (Leidel *et al*. 2015).

On this basis, we conducted a trial of opt-out HIV testing using a theoretical framework specifically developed to inform this study (Leidel *et al*. 2017). The framework integrates concepts from Behavioural Economics (Rice 2013), the foundation for the default-based (opt-out) study intervention; the Health Belief Model, to explore possible relationships between the participants’ beliefs about HIV and their testing practices (Rosenstock 1974); and Normalisation Process Theory, a guide for implementation of opt-out HIV testing at the operational level (May 2013).

We conducted this study at Homeless Healthcare, a unique general practice in inner-city Perth, Western Australia. Homeless Healthcare runs street-based mobile clinics led by GP–nurse teams, providing health care for ~3000 homeless and marginalised patients each year. Its outreach service is led by a ‘street health’ nurse who identifies vulnerable people with urgent health needs and connects them to the mobile clinics, which are spread across seven different locations. Homeless Healthcare also runs a conventional GP surgery for people whose housing situation becomes more stable and an ‘in-reach’ service for homeless patients who are hospitalised. Risky behaviours that could result in HIV infection (such as injecting drug use) are common within the Homeless Healthcare patient cohort, so it was considered to be a valid site to explore opt-out testing. Our aims were to: (1) determine the effect of the opt-out approach on the number of HIV tests performed; and (2) explore the acceptability and feasibility of opt-out HIV testing from the healthcare providers’ perspective.

What is known about the topic?

- Opt-out HIV testing outside of Australia is acceptable to healthcare providers and has been shown to identify undiagnosed HIV infections.

What does this paper add?

- In the first study of opt-out HIV testing in Australia, healthcare providers in an Australian general practice for marginalised patients found the approach to be feasible and acceptable.

Methods

A prospective mixed-methods study of opt-out HIV testing was conducted at Homeless Healthcare over a 2-year period. Participants included GPs, nurse practitioners (NPs) and nurses (nurses were included because they take part in every consult at Homeless Healthcare, and their involvement has been shown to facilitate the implementation of opt-out HIV testing) (Leblanc *et al.* 2015). In the first phase (March 2014–March 2015), the healthcare providers conducted HIV testing according to their usual practice. They were not informed of the number of HIV tests that they performed during that year. In March 2015, we educated the same cohort of healthcare providers about opt-out HIV testing. During the intervention year (April 2015–April 2016), these providers performed opt-out HIV testing on patients having other blood tests (e.g. 'we are going to test you for HIV unless you do not want to be tested'). If the patient did not opt-out, the healthcare provider obtained a blood sample by venepuncture, which was sent to a laboratory and tested with a HIV-1 and -2 antibody and antigen assay. The participants did not record the number of HIV tests that they performed and did not receive feedback about their testing practice during the intervention. At the end of the intervention, we obtained de-identified HIV testing data from the laboratory that performs all blood testing for Homeless Healthcare. We then compared the number of HIV tests done before the intervention (usual practice) and during the intervention (opt-out testing).

To explore the healthcare providers' experiences with opt-out HIV testing, we interviewed the participants after the intervention period. A semi-structured interview guide and coding scheme was developed according to our opt-out HIV testing theoretical framework (Appendix 1) (Leidel *et al.* 2017) The primary researcher de-identified, transcribed and coded the interviews using directed content analysis (Hsieh and Shannon 2005). An experienced qualitative researcher (SG) then reviewed the coding. We resolved coding discrepancies through discussion. Data were managed with NVivo (ver. 11, QSR International, Melbourne, Vic., Australia). This study was approved by the Human Ethics Research Committee of the Faculty of Health Sciences, Curtin University, Perth, Western Australia, Australia.

Results

Number of HIV tests performed: usual practice versus opt-out

Three GPs, four practice nurses and one nurse practitioner provided written consent to participate in the study, representing the majority of clinic staff. From 1 April 2014 to 31 March 2015, the participating GPs and NP conducted HIV testing according to usual practice. During this period, they conducted 9932 patient visits, of which 2594 were unique patients. They performed 6039 laboratory tests, of which 315 were HIV tests (12% of the patients at Homeless Healthcare had HIV tests). There was one positive result (Fig. 1).

Between 1 April 2015 and 31 March 2016, the same cohort of providers conducted HIV testing on an opt-out basis for patients who were already having blood tests. During this period, there were 10 663 patient visits, of which 3316 were unique patients. They performed 6030 laboratory tests, of which 344 were HIV

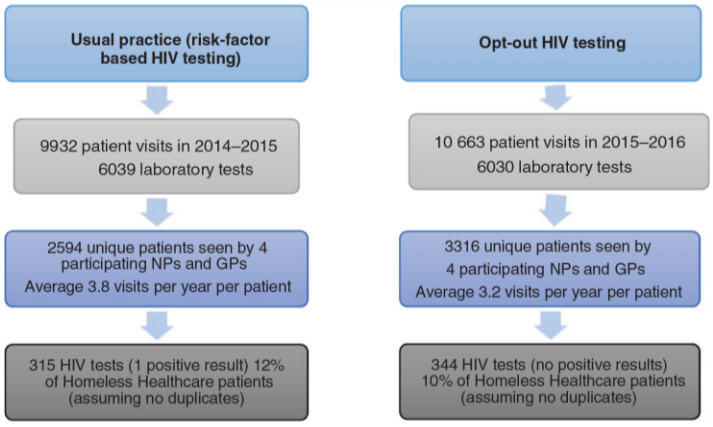

Fig. 1. Number of patients, visits and HIV tests at Homeless Healthcare before and during opt-out testing.

tests (10% of the patients at Homeless Healthcare were tested). There were no positive results.

Qualitative findings

After the intervention year, in May and June 2016, the primary researcher (S. Leidel) interviewed the eight participants by a video chat application. Interviews ranged from 20 to 44 min. By the eighth interview, no new concepts were surfacing.

We present the healthcare providers' experiences according to selected concepts (Fig. 2) from our opt-out HIV testing theoretical framework; these concepts were: HIV testing by default, provider self-efficacy, collective action and coherence, perceived barriers and perceived benefits (Leidel *et al*. 2017).

HIV testing by default

Participants said that the change to opt-out HIV testing (which is done without pre-test counselling) was not difficult. They found that patients did not expect an explanation other than being informed they would be tested for HIV test unless they declined.

> I started saying we're doing opt-out testing for HIV, and I tried to explain it, and I just got weird looks [GP-3].

Offering HIV testing as a default meant that the healthcare providers did not enquire about the patients' risk factors, treating the HIV test like other routine blood tests. Deferring the risk factor assessment conveyed an open-minded attitude to patients and saved time and effort by taking 'that decision-making off our shoulders' [RN-1].

> It's just part of providing a non-judgmental service [NP-2].

> It actually gave us more time, because we didn't have to dance around it [RN-1].

> It made it easier because it wasn't a matter of querying which clients were going to be offered it or not, it was just a routine thing [RN-7].

Provider self-efficacy with opt-out HIV testing

Some participants stated that they were initially uncomfortable with opt-out HIV testing, but quickly became confident with it.

> During the study period, I had my first ever positive HIV test. So that increased my confidence because I actually went through the process of referring [GP-5].

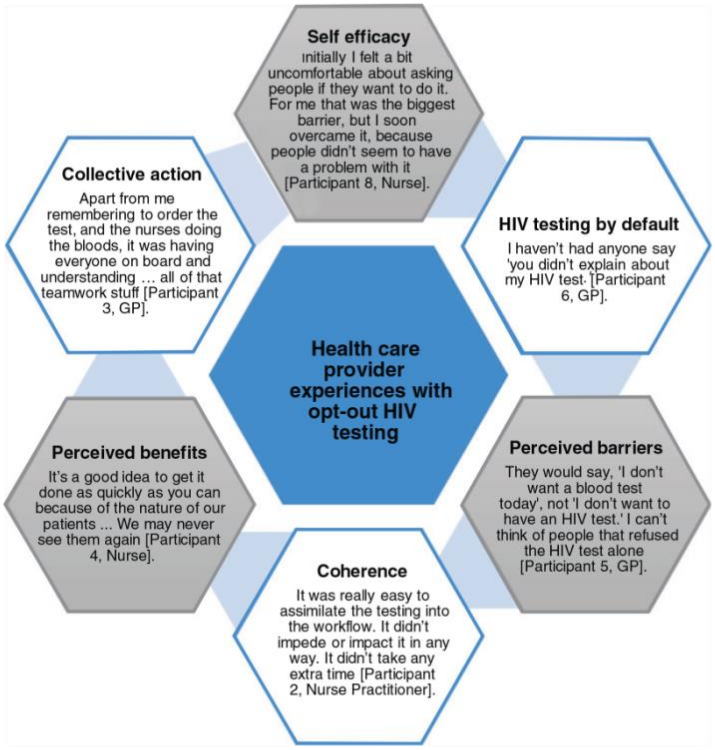

Fig. 2. Healthcare providers' views on opt-out HIV testing according to our theoretical framework.

Participants sometimes asked the patients if they would like to be tested for HIV, rather than informing them that they would be tested unless they declined. This subtle difference in syntax indicated a lack of self-efficacy with making opt-out statements.

> We are doing these bloods, so do you want these [HIV] bloods as well? [NP-2].

Two GPs said that they had previously been doing a version of opt-out to facilitate HIV testing without recognising it as a distinct approach.

> I've probably been unwittingly doing opt-out testing for a number of years, and in our client population, I've found that's the easiest way to go [GP-6].

Coherence and collective action in the implementation of opt-out HIV testing

Teamwork among healthcare providers facilitated the opt-out HIV testing program, particularly between the GPs–nurse teams running each mobile clinic.

> In our practice we have the luxury of working really closely with nurses. I didn't need to say 'we're doing a HIV test', because the nurses see that it needs to be done [GP-5].

> It didn't matter who you were working with, things were done in unison, there was teamwork, and it was you do this, I do that [RN-4].

Perceived barriers to opt-out HIV testing

Participants rarely encountered barriers to opt-out HIV testing. The most common barriers were provider discomfort with talking about HIV and convincing patients to have blood tests. Most participants said that no one opted out of HIV testing.

> In the beginning the only barrier was feeling a bit uncomfortable doing it. I don't think I ever had someone say no, except for one who already had HIV [NP-2].

> The barrier was convincing people to have blood tests. If they were willing to have a blood test, they were willing to have an HIV test [GP-6].

Discussion

HIV testing rates were low among Homeless Healthcare patients during the control year (usual practice) and the intervention year (12 and 10% respectively). Given that up to 21% of HIV infections in Australia are undiagnosed (The Kirby Institute 2014), our data show that HIV testing rates could be improved, even in services like Homeless Healthcare that specialise in the treatment of marginalised groups. Other studies have found low HIV testing rates in high-risk groups, such as Indigenous Australians (Ward *et al*. 2016). Since 2011, notifications of HIV among Indigenous Australian males have increased steadily compared to non-Indigenous, Australian-born males, supporting the need for novel testing approaches (The Kirby Institute 2016).

The number of HIV tests performed with usual practice and the opt-out approach were remarkably similar. One reason may be that some of the participants had started to abbreviate pre-test counselling and risk factor assessment before the intervention began, essentially performing opt-out testing without recognising it as a shift in practice. Some participants did not always use the exact opt-out wording that they had learned for the pilot test, or phrased the opt-out statement as a question when gaining consent (Australasian Society for HIV Medicine 2014). They may have been uncomfortable with opt-out HIV testing even if they supported it conceptually, perhaps because they were taught to do pre-test counselling during their training and it had become embedded in their practice. Discomfort with introducing HIV tests to patients has been documented among nurses doing opt-out HIV testing in several countries (Evans *et al*. 2015) and among healthcare providers in the US (Christopoulos *et al*. 2011). Providers who were less comfortable with the opt-out approach may have done fewer HIV tests because they modified the way the test was offered, contributing to the reasonably constant number of opt-out HIV tests compared to usual practice.

Access to health care is associated with increased HIV testing (Thomas *et al*. 2010). In our study, the number of HIV tests did not increase during the opt-out period, which may be related to the patients' access to health care; some patients may not have had blood tests during the study period because they had already been tested for HIV. By offering non-judgemental services in areas of greatest need, Homeless Healthcare is able to engage marginalised people who would not normally have access to health care. With each patient having an average of three GP visits per year, homeless individuals had an opportunity for health screening (including HIV testing) and harm-reduction education, which may have been a factor in the low incidence of HIV in this study.

The number of HIV tests performed with the opt-out method did not decrease substantially from the previous year, suggesting that few patients opted out of HIV testing. Although this study was not designed to capture the number of patients who opted out, most participants stated that patients rarely declined (except for people who did not want to have blood tests done at all or reported that they were HIV positive). Studies from diverse settings around the world have shown high patient acceptance of opt-out HIV testing (Haukoos *et al*. 2008; Wilson d'Almeida *et al*. 2013; Montoy *et al*. 2016). This is the first Australian study to demonstrate that marginalised patients are accepting of the opt-out method.

Our previous study of Australian healthcare provider views on opt-out HIV testing identified a subset of healthcare providers who thought that it was not feasible or acceptable (Leidel *et al*. 2015). This study demonstrated that the opt-out approach is feasible and acceptable to healthcare providers and patients in a general practice that focuses on at-risk patients. Consistent with international research findings, opt-out HIV testing did not disrupt workflow or impede other clinical activities (Solomon *et al*. 2014). The healthcare providers in this study reported that the opt-out HIV testing program was easy to implement, saved time and removed the task of performing a risk assessment and pre-test counselling on every patient.

Our findings also add to the body of evidence showing Australia's successful response to its HIV epidemic. We found a very low incidence of HIV in a general practice with over 3000

vulnerable patients (many of whom likely engage in high-risk behaviours), highlighting the undeniable achievements in HIV prevention in Australia. New HIV infections peaked in Australia in 1987 and decreased steadily until 1999 (The Kirby Institute 2014), largely due to the success of needle syringe programs, preventing an explosion of infections among injecting drug users (Madden and Wodak 2014). Decriminalisation of the sex industry and empowerment of sex workers has also contributed to Australia's low HIV prevalence (Bates and Berg 2014). HIV prevention initiatives, particularly school-based youth education campaigns, were instrumental in decreasing risk behaviours (Jones and Mitchell 2014). Despite these achievements, the small but steady rise in HIV infections over the past 17 years (The Kirby Institute 2014) indicates that new approaches (such as opt-out testing) are needed to sustain Australia's low HIV prevalence. Although this study has provided a preliminary view on opt-out HIV testing in the Australian context, the value of the approach should be studied across different groups. Patient acceptability of opt-out HIV testing should be investigated.

Limitations

We did not obtain HIV testing data on individual patients, so it is possible that some patients were tested more than once (which is appropriate if they are at a high risk of infection), although duplicate tests would be unlikely to vary substantially from year to year. We were also unable to identify patient-initiated HIV tests from the laboratory data. Because the healthcare providers performed opt-out testing only on patients who were already having blood tests, we may not have captured the entire cohort of patients who could be HIV positive. Patients at highest risk of HIV infection may have been less likely to agree to any blood test. Rapid point-of-care HIV tests, which were approved in Australia in 2012 and do not require venepuncture, may help overcome this barrier (Chan *et al*. 2015). Whereas opt-out HIV testing was easily implemented in this particular general practice, we cannot make inferences about its acceptability or feasibility in other health services.

Conclusion

We found that opt-out HIV testing was feasible and acceptable to healthcare providers in an Australian general practice that specialises in care for homeless and marginalised people. The number of HIV tests did not change substantially with the opt-out approach, suggesting that few patients opted out. Based on our findings, Australian health services could consider testing the feasibility of opt-out HIV testing for their patients (or a subgroup of patients) as a viable way to identify people with undiagnosed infections. Identifying these individuals and connecting them to HIV care would improve health outcomes and decrease onward transmission of the virus, which is necessary to sustain Australia's low HIV prevalence.

Conflicts of interest

The authors declare that they have no conflicts of interest.

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Appendix 1. Interview guide for healthcare providers (HCPs) (conducted after the opt-out HIV testing study)

1. Describe your experience with opt-out HIV testing.
   a. Prompts: time factors, resource constraints, issues related to pre-test counselling.
2. What facilitated the process of opt-out HIV testing?
   a. Prompts: computer reminders, education sessions, staff engagement.
3. What barriers did you encounter?
   a. Prompts: disrupted workflow, patients' lack of willingness, time constraints.
4. Did you have ethical concerns during the opt-out testing process?
   a. Prompts: informed consent, confidentiality, privacy.
5. How do you think the default option affected the number of HIV tests that were performed?
6. How did you 'frame' the opt-out HIV test for your patients?
7. Did your beliefs about your patients' susceptibility to HIV change during the pilot test? If so, how?
8. What cues or reminders were helpful during the pilot test? [cues to action]
9. How confident are you that you can perform opt-out HIV testing, discuss results with patients and make referrals if needed? Did this confidence increase during the study period? [self-efficacy]
10. Describe how opt-out HIV testing became part of day-to-day practice. [coherence]
11. Describe how the HCPs worked together to perform opt-out HIV testing. [collective action]

CHAPTER 6

DISCUSSION

This thesis presents the first trial of opt-out HIV testing in Australia. Opt-out HIV testing abbreviates the pre-test counselling, history-taking and risk factor assessment process advocated by current Australian HIV testing recommendations (Australasian Society of HIV Medicine, 2014). The overall aim of this thesis was to inform a possible change in HIV testing practice by exploring health care providers' views on opt-out HIV testing in a qualitative study, then by analysing their acceptance of the approach after implementing it in a primary health service. The overarching framework was Implementation Science, the process of translating research evidence into clinical practice, including needs assessment, planning, feasibility studies, and ongoing evaluation (Hargreaves et al., 2016; van Bon-Martens et al., 2016). Although there were mixed opinions about opt-out HIV testing in the qualitative study, when implemented in a primary health care service, health care providers found it acceptable and identified few barriers.

The research project began with the first step in Implementation Science processes: a needs assessment exploring the current state of HIV in Australia, identifying a recent increase in HIV diagnoses, particularly through heterosexual transmission. This needs assessment article (Leidel et al.,2015, *Australasian Medical Journal*) analysed international evidence supporting opt-out HIV testing to identify undiagnosed infections. Numerous studies suggested that opt-out HIV testing was effective at identifying HIV infections (Montoy et al., 2012; Nayak, Welch & Kan, 2012) and was acceptable to health care providers (Bath et al., 2015; Navaza et al., 2016; Simmons et al., 2011), although no Australian studies about the approach were identified.

The next phase of the research was a systematic review (Leidel et al., 2015, *AIDS Care)* exploring international health care providers' experiences with opt-out HIV testing, revealing two new themes: *Attitudes* and *Systems. Attitudes* captured health care providers' beliefs about opt-out HIV testing, and *Systems* referred to operational barriers and facilitators to the implementation of opt-out HIV testing programs. These themes laid a foundation for the subsequent original research about opt-out HIV testing in Australia.

Following these literature reviews, a qualitative study of Australian health care providers' views on opt-out HIV testing was undertaken (Leidel et al., 2015, *BMC Public Health*). About half the participants supported opt-out HIV testing, while the other half was

less accepting, citing a lack of Australian evidence supporting the approach. Two contrasting themes emerged: *Normalisation and Routinisation* versus *Exceptionalism*, and *Need for Proof* versus *Openness to New Approaches*. Qualitative analysis of the health care provider interviews was informed by the Health Belief Model (health care providers' beliefs about HIV) and Behavioural Economics (the effect of default-based testing).

Next, the Health Belief Model and Behavioural Economics were merged with Normalisation Process Theory (which addresses the operational factors related to opt-out HIV testing) to create a comprehensive theoretical framework. These theories corresponded to the planning stage of the Implementation Science process. Development of the framework was examined in a separate study (Leidel et al., 2016, *Journal of Evaluation in Clinical Practice*). The framework guided qualitative data analysis in the final phase of the research.

The culmination of the research and theoretical exploration was a prospective, mixed-methods study of opt-out HIV testing in a primary health care service in Western Australia (Leidel et al., 2017, *Australian Journal of Primary Health*). Consistent with the feasibility study and evaluation stages of the Implementation Science process, the effect of the opt-out approach on HIV testing rates was investigated over a 12-month period and compared to usual HIV testing practice in the previous year. The opt-out approach did not affect testing rates, suggesting few patients opted out. The participating health care providers were interviewed about their experiences with opt-out HIV testing, generally describing the approach as acceptable and feasible. This final study provided initial evidence of the feasibility of opt-out HIV testing in an Australian setting which could inform opt-out HIV testing programs in other populations, or opt-out testing for other conditions.

Review of the research objectives as they related to the findings

The objectives of this research were addressed in a series of publications commencing with a needs assessment about opt-out HIV testing in Australia, progressed through literature reviews and theoretical analysis, and ended with the first Australian study of the approach in a primary health service. It is worth noting that the objectives evolved in response to data analysis and peer review as the research progressed.

The first three objectives of this research project explored health care providers' beliefs and acceptance of opt-out HIV testing, with a goal of developing a typology that could inform implementation and evaluation of the practice. Beliefs were associated with acceptance of opt-out HIV testing in the systematic review, the qualitative study, and the final

trial (e.g., health care providers with a positive attitude toward opt-out HIV testing accepted the practice, whereas providers who had less favourable attitudes did not accept it).

The first paper (Leidel, et al., 2015, *Australasian Medical Journal*) identified potential benefits of opt-out HIV testing based on Australian HIV data and international experience with the approach. Research from the US indicated that opt-*in* HIV testing was not effective at preventing late HIV diagnosis, leading to the recommendation for opt-*out* HIV testing (Branson et al., 2006). Steady increases in HIV diagnoses in Australia since 1999 coupled with an increase in heterosexual transmission suggested that a change in testing approach could be beneficial (The Kirby Institute, 2014). With this context in mind, this research sought to explore opt-out HIV testing from an Australian context (which had not yet been studied) to inform a possible change in testing recommendations.

The second paper (Leidel et al., 2015, *AIDS Care*) expanded on the first article with the first systematic review of qualitative research on international health care providers' attitudes toward opt-out HIV testing. Prior research focused on developing countries (Kennedy et al., 2013) or used quantitative or mixed-methods (Christopoulos et al., 2011; Glover Rucker et al., 2016; Harmon, Collins-Ogle, Bartlett, Thompson, & Barroso, 2014; Haukoos et al., 2010). Qualitative research was a potentially rich source of health care providers' beliefs and experiences that could not be fully explored with quantitative methods. A theme-driven evidence base about health care providers' views on opt-out HIV testing was not yet well developed. Themes from this systematic review would inform the subsequent study of health care providers' views and the trial of opt-out HIV testing.

Following this systematic literature search, the quality of the evidence was appraised and findings were synthesised, leading to the development of two overarching themes: *Attitudes* and *Systems*. Health care providers' decision making was influenced by their attitudes about opt-out HIV testing as opposed to empirically-based guidelines, affecting who was tested and in what circumstances. System factors such as time, resources, and funding created barriers to opt-out HIV testing. Insufficient time (or a perceived lack of time) was identified as a barrier in numerous studies on opt-out HIV testing (Arbelaez et al., 2012; Johnson, Mimiaga, Reisner, Van Derwarker, & Mayer, 2011; Mimiaga, Johnson, Reisner, Vanderwarker, & Mayer, 2011; Rizza, MacGowan, Purcell, Branson, & Temesgen, 2012). Research published after this review continued to identify lack of time as a major barrier to full implementation of opt-out HIV testing (Osorio et al., 2017). Although time was a systems-related factor, it may have been related to attitudes (e.g., some health care providers did not see opt-out HIV testing as a priority in their practice, and therefore did not allocate

time to it). Common facilitators of time management reported in other studies not covered by the systematic review were electronic reminders (Brennan et al., 2013; Marcelin et al., 2016; Schnall et al., 2014) and organisational support (Czagornski, 2013; Hood, Robertson & Baird-Thomas, 2015; Lo et al., 2013).

The third paper, (Leidel et al., 2015, *BMC Public Health*) narrowed the focus from international health care providers to a group of primary health care providers in Western Australia; particularly *Attitudes* and *Systems,* which might influence the adoption of opt-out testing. Before this study, Australian health care providers' beliefs and attitudes toward opt-out HIV testing were unknown. Australia's only experience with the opt-out approach was the 2006 guideline recommending opt-out HIV testing for pregnant women (Giles, Hellard, Lewin & Mijch, 2006; Royal Australian New Zealand College of Obstetrics & Gynaecology [RANZCOG], 2015), but no studies about Australian health care providers' views on opt-out HIV testing for the antenatal population were found. Although there was no evidence that the 2006 RANZCOG guideline was controversial, it was clear there was a gap in knowledge about Australian health care providers' attitudes toward opt-out HIV testing.

The first contrasting theme that emerged from the study was *Normalisation and Routinisation* (treating HIV like other chronic diseases) versus *Exceptionalism* (treating HIV differently, for example requiring separate written consent for HIV testing). This finding is comparable to previous research suggesting a dichotomy between HIV exceptionalism and the normalisation of opt-out HIV testing (Bayer & Fairchild, 2006; De Cock & Johnson, 1998). Most participants in this study favoured either *Normalisation and Routinisation* or *Exceptionalism* instead of more nuanced views (like normalising HIV testing in some settings and not others). Participants in previous studies held similar views; in some cases, stating that *Normalisation* through the opt-out approach was a solution to the problem of HIV *Exceptionalism* (Smith & Whiteside, 2010). Other participants concurred with researchers arguing that HIV should be treated differently because of its associated stigma (April, 2010; Evans & Ndirangu, 2009). In the final study in this research project, participants cited normalisation as a benefit of the opt-out HIV testing program; their attitudes did not reflect HIV exceptionalism, suggesting that the experience of opt-out testing normalised HIV testing for health care providers.

The second contrasting theme from the qualitative study was *Openness to New Approaches* versus *Need for Proof.* Some participants were already taking an opt-out approach to HIV testing or were open to the idea. Others identified barriers like an irrelevance to Australia, insufficient evidence in favour of the approach, and low perceived HIV risk in the

providers' patient population, which have been reported in other studies (White & Walsh 2015). However, participants in prior research about opt-out HIV testing had not identified relevance to one country over another as a barrier. As in the systematic review in this thesis, participants who were less accepting of opt-out HIV testing mentioned time as a barrier.

Many participants had reservations about opt-out HIV testing because the evidence in favour of the practice was from international research. However, some participants stated that if supporting evidence for opt-out HIV testing in Australian settings emerged, they would consider adopting the approach but did not suggest specific ways to gather this evidence. Participants in other studies of opt-out HIV testing did not suggest pilot tests either, which was a surprising finding because practice changes are often initially tested on a small-scale (Bath, Ahmad, & Orkin, 2015; Costello et al., 2013; O'Connell et al., 2016). Given the weight of international evidence, using an Implementation Science framework, this pilot study could provide evidence before broader implementation was considered. Participants' comments about the lack of evidence supporting opt-out HIV testing highlighted the importance of starting an evidence base about the approach in Australia.

In view of health care providers' beliefs about evidence for opt-out HIV testing, the next step was to construct their health belief typology relating to the approach in their patient population. The typology would be comprised of the categories of health care provider beliefs that emerged from the qualitative data and could inform subsequent research, theory development, and policy. Other researchers have used theory to guide implementation of opt-out HIV testing (Kok, et al., 2015; Leon, 2014) but literature reviews for this thesis did not identify any research developed around an original typology or theoretical framework. In order to address this, health care provider beliefs in the qualitative study were initially analysed per the Health Belief Model. Next, the analysis expanded from beliefs to Behavioural Economics, the study of the effects of defaults (e.g., choices that are made automatically, unless an alternative is chosen) on decision making.

As data analysis and peer review of the qualitative study progressed, it became clear that opt-out HIV testing was not affected solely by health care providers' beliefs or by default-based decision making. Therefore, the typology needed to expand beyond Behavioural Economics and the Health Belief Model to a broader theoretical framework. Operational factors (described by Normalisation Process Theory) also influenced the uptake of opt-out HIV testing. Other studies of opt-out HIV testing have been guided by Normalisation Process Theory (Leon, Lewin, & Mathews, 2013). A novel theoretical framework integrating Behavioural Economics, the Health Belief Model, and Normalisation

Process Theory was then developed and described in the fourth publication, (Leidel et al., 2016, *Journal of Evaluation in Clinical Practice)*. The framework was used as a coding scheme for the qualitative data analysis in the final study verifying the utility of the framework, which presents a unique feature of this thesis that may be useful to other researchers and a key component of well-designed Implementation Science.

Although the theoretical framework worked well for the research presented in this thesis, additional theories may have enriched the research design and data analysis. For example, organisational change theory might have added the idea of a change agent or champion guiding the other participants to implement the new process (McCormack et al., 2013). Organisational Change Theory and Normalisation Process Theory are similar because both theories pertain to collaboration among health care providers to implement practice changes. Further, Organisational Change Theory could have built on individual beliefs from the Health Belief Model to explore the influence of organisational culture on the implementation of opt-out HIV testing. For example, instead of focusing on individual opinions, participants could have been asked about opt-out HIV testing in relation to cultural norms within the organisation (Weiner, 2009). The stages of change concept from organisational change theory could have been used to analyse individual participants' characteristics and their effect on implementation (Braithwaite et al., 2014). For example, and as noted previously, the participants in the final study may have been *Early Adopters*, accounting for their mostly positive experiences with opt-out HIV testing (Sullivan, Ibrahim, Ellner, & Giesen, 2016). The idea of *Early Adopters* was similar to the *Openness to New Approaches* theme identified in the qualitative study, though these themes contrasted with the health care providers who required supporting evidence for opt-out HIV testing before implementation.

The final study further narrowed the research focus to a specific primary health care service in Western Australia, to determine if the opt-out approach increased HIV testing rates, and to evaluate its acceptability among health care providers. After a 12-month trial of opt-out HIV testing, the participating health care providers were interviewed about their experiences. Consistent with numerous studies from around the world, they reported high degrees of acceptability and self-efficacy with opt-out HIV testing, identified numerous facilitators to the program (like regular meetings and reminders), and reported few barriers (Kayigamba et al., 2014; Navaza et al., 2016).

The providers' acceptance of opt-out HIV testing in the final study contrasted with the less accepting participants in the previous qualitative study (Leidel et al 2015, *BMC Public Health)*. The participants in the trial of opt-out HIV testing (Leidel et al 2017, *Australian*

Journal of Primary Health) did not mention a need for evidence for the practice before implementation, suggesting they were more open to changing practice (Leidel et al., 2015, *BMC Public Health*). This may reflect different individual attitudes and understanding (e.g., there were fewer early adopters in the qualitative study) or an organisational culture favouring new practices, or both. Participants in the trial of opt-out HIV testing frequently mentioned the benefits of normalising HIV testing with the opt-out approach; unlike the previous study, views favouring HIV exceptionalism did not emerge.

Part of the project was to design and trial an opt-out model of HIV testing in a primary health care setting (in this case Homeless Healthcare) and explore health care providers' experiences with the change in practice. Although linkage to care was a common concept in the HIV literature (Sanchez et al., 2014; Seth et al., 2015), a specific linkage to care protocol applicable to a Western Australian (or Australian) health service was not identified. Therefore, a linkage to care protocol (Appendix 8) was developed during the design of the opt-out HIV testing project to be used in case of a positive HIV test during the study. Development of the linkage to care protocol involving staff from the referring health service and the HIV Medicine service was an important feature of this research project not commonly discussed in the existing literature on opt-out HIV testing. Ad hoc linkage to care was typically defined in terms of viral load or CD4 count, used different time frames for follow-up, and lacked a detailed description of the referral process (Coyle & Kwakwa, 2016; Hennessey et al., 2013; Leon et al., 2014). The protocol for this study could be used to guide other researchers or health care providers considering an opt-out HIV testing program and could be applied to other health conditions requiring prompt specialty referral.

The last study in this thesis, (Leidel et al., 2017, *Australian Journal of Primary Health*) was a prospective trial of opt-out HIV testing in a primary health care service. Compared to usual practice, opt-out HIV testing did not affect the number of HIV tests performed, a finding supported by previous research (Darling et al., 2012) but contrasting with other studies that found increased testing rates with the opt-out approach (Byamugisha et al., 2010). Similar testing rates between opt-*in* and opt-out testing suggested (like numerous other studies) that few patients opted out (Hankin, Freiman, Copeland, & Shah, 2014; Haukoos et al., 2013).

The final intervention of this research project was implemented without major problems, making it difficult to analyse potential drawbacks of opt-out HIV testing. In contrast to other studies of opt-out HIV testing (Galbraith et al., 2016), there were no adverse events during the intervention that required changes in the design of the trial. Based on other researchers'

experiences with opt-out HIV testing, it was expected that the opt-out HIV testing intervention would need to be modified during implementation (Christopoulos et al., 2011; Hennessey et al., 2013). For example, if the GPs did not have time to do opt-out testing, changes in practice may have been required, such as creating standing orders for nurses to do HIV testing (Davyduke, Pietersen, Lowrance, Amwaama, & Taegtmeyer, 2015; Evans et al., 2014). Whilst the participants did not propose changes to the opt-out HIV testing process during this study, it has been reported elsewhere that staff have felt uncomfortable without adequate training when adopting this testing approach (Davyduke et al., 2015; Evans et al., 2014).

Few barriers documented in other research, such as low provider self-efficacy, were encountered in this study (Akhter, Gorelick & Beckmann, 2012; Coeller, Kuo & Brown, 2011). The health care providers may have accepted opt-out HIV testing because it was easily implemented. There was only one positive HIV test and no adverse events to interrupt their routine or increase their workload. If there had been more positive HIV tests, the participants may have had different views. For example, if staff resources and time were too scarce to manage post-test counselling, coordination of care, reporting to health authorities, and contact tracing, the providers' experiences may have been less positive. Adverse events like failing to link an HIV-positive patient to specialised care, which has been noted in previous research (Coyle & Kwakwa, 2016; Galbraith et al., 2016) could also have decreased acceptability. Conversely, because the health care providers agreed that opt-out HIV testing was acceptable, and there were few negative consequences, the approach could be acceptable if adopted more widely. The possibility of identifying more HIV infections, and therefore improving patients' and the public's health, could be a motivator to continue opt-out HIV testing.

Limitations

The research presented in this thesis had several limitations. One weakness was the homogeneity of the setting and participants. The qualitative study was conducted in one Australian state with participants from mostly urban areas who may not have represented the full spectrum of beliefs and attitudes about opt-out HIV testing. However, qualitative methods were appropriate because this was the first exploration of opt-out HIV testing in Australia and the themes, barriers, and facilitators were unknown (Greenhalgh et al., 2016). The final prospective study of opt-out HIV testing took place in one health care organisation. Although the same cohort of health care providers conducted the testing at all sites, seven different primary healthcare locations were represented in this study. Further studies exploring opt-out HIV testing could expand to other health settings and include a larger sample of participants.

It is possible that the theoretical framework developed for this research would have been more robust with the inclusion of organisational change theory. Organisational culture probably influenced the implementation of opt-out HIV testing, and this social dimension merited further exploration. The theoretical framework has only been used for the small-scale study in this thesis; it could be evaluated in different settings or in larger populations. Expanding exploration of the theoretical framework in other opt-out HIV testing programs could be part of the ongoing, post-intervention evaluation aspect of the Implementation Science process.

Another limitation was that the research did not include patient views, which were commonly included in research about opt-out HIV testing (Cowan et al., 2013; Favre-Bulle et al., 2015, Schechter-Perkins et al., 2015) and could have enriched the analysis. The literature review identified major concepts (like pre-test counselling, consent and stigma) which were explored from the health care providers' perspectives. The qualitative study of health care providers identified themes like *Normalisation*, but it is not known if patients thought the opt-out approach normalised HIV testing. Although the opt-out approach did not affect the number of HIV tests performed, Australian patient perceptions about opt-out HIV testing are unknown. Prior research on opt-out HIV testing commonly found high levels of patient acceptance, typically defined as the number of tests completed compared to the number of tests offered (Mignano et al., 2016, Rucker et al., 2016; Rutstein et al., 2016). In some cases, patients were more accepting of opt-out HIV testing than health care providers, who ironically appeared to be more concerned about privacy and consent than patients (White, Anderson, Pfeil, Graffman, & Trivedi, 2016).

Future directions and impact

This thesis presents an initial exploration of opt-out HIV testing that could guide further research and future implementation science guiding HIV testing practices. A broader range of methodologies and theoretical perspectives would make the evidence base for HIV testing changes more robust. For example, additional research could inform HIV testing policy development at local, state and federal levels of government. Non-governmental professional organisations could refer to this evidence when writing new guidelines. Selected issues that emerged from the literature reviews and original research are presented here as possible future directions for research on opt-out HIV testing in Australia.

Pre-test counselling

There was limited evidence on the effect of omitting pre-test counselling in the literature about HIV testing in Australia. Now that home-based HIV testing is available, the consequences of testing without pre-test counselling need to be explored. In the final study presented in this thesis, health care providers were in favour of leaving out pre-test counselling. Attitudes about omitting pre-test counselling should be explored in more depth from both health care provider and patient perspectives. Educational efforts to change health care provider behaviour (e.g., brief detailing sessions about the minimal effect of health education on behaviour) could be designed and tested. Future studies could explore patients' baseline knowledge about HIV prior to opt-out testing to explore potential associations between knowledge and acceptance of the opt-out approach.

Avoiding classification errors

Studies reviewed for this thesis identified potential classification errors with opt-out HIV testing: some patients did not know that the opt-out approach was voluntary, potentially leading to adverse events. A positive HIV test in a person who did not know he or she was tested could lead to negative consequences. Future research could also explore how health care providers should convey the message that patients are free to decline testing. Another classification error identified in the literature review was patients' belief that they were tested for HIV when they were not tested. The causes of this belief and potential solutions could be explored. Future research could be designed to control for classification errors.

Special situations

Opt-out HIV testing has not been explored in specific risk-related situations. For example, the literature review conducted for this thesis found no studies on opt-out HIV testing in the setting of a sexual assault. If victims present to health services for treatment after a sexual assault, they are typically offered pregnancy testing (for females) and testing for sexually transmitted infections, but there was no consensus on best practices for this situation. Opt-out HIV testing may lead to increased testing and identify more HIV infections after assault but may be inappropriate for a person in an already vulnerable condition. Sexual assault victims, advocates, and/or clinicians could be interviewed to explore the moral, legal and ethical issues with opt-out HIV testing in that situation.

Another direction for future research could be opt-out HIV testing in the setting of accidental occupational exposure, a common trigger for HIV testing that was not studied in

the present research. An opt-out approach could streamline this potentially stressful process, but omitting pre-test counselling could cause patient distress. Studies investigating people's preferences for pre-test counselling in this situation could guide practice. The effect of opt-out HIV testing on patient anxiety in stressful circumstances may merit further study.

Opt-out HIV testing has not been studied in specific cultural or linguistic groups in Australia. The patient population at the study site in this project was multicultural, but cultural and linguistic factors were not investigated. Future research could investigate cultural and linguistic influences on the uptake of opt-out HIV testing. For example, if members of a cultural group believe that health care providers are authority figures, they may be more likely to accept the HIV test, resulting in a classification error (in which people who do not want to be tested are tested).

For the health care providers in previous studies as well as the present research, communicating with patients about opt-out testing was important (Walensky et al., 2011; Albrecht et al., 2012). Health care providers should offer the HIV test as the default while still presenting the test as voluntary. Participants in this research project did not always use the exact opt-out wording when offering the HIV test, as in some previous research (Montoy 2016). Patients whose first language is not English may not understand the subtle difference between opt-*in* and opt-*out* testing, potentially resulting in a classification error. Interpreters (if they are available at the time of testing) may not convey the meaning of opt-out HIV testing adequately. Before implementing opt-out HIV testing in a culturally or linguistically diverse group, these issues should be studied to identify best practices.

The present research was conducted in a general practice setting in which the patients were typically competent to consent to treatment. Previous research typically excluded patients who were not able to consent (Haukoos et al., 2012). Little is known about opt-out HIV testing in situations in which patients cannot give consent and should be explored. The literature review identified situations in which opt-out HIV testing has not been studied, such as severe mental illness, mechanical ventilation, or intoxication. International evidence indicated that family members wanted to provide consent for severely ill patients (Martin et al., 2015), but this finding has not been replicated in other studies and has never been investigated in Australia.

Research on consent in special situations could also include ethical implications of opt-out HIV testing. In the qualitative study of Australian health care providers' views on opt-out HIV testing, ethical issues did not emerge as themes, although other researchers and commentators had reported ethical concerns (Merchant & Waxman, 2012). After the trial of

opt-out HIV testing in this study, health care providers were asked if they had any ethical concerns with the approach, but no concerns were expressed. Future studies could explore these issues in different settings or with a larger sample.

Opt-out HIV testing did not lead to higher testing rates in the final trial of this research project, possibly because the baseline prevalence in Australia was low. To expand opt-out HIV testing, research in higher HIV-prevalence areas is needed. Australia's HIV epidemic is concentrated primarily among men who have sex with men (The Kirby Institute, 2016). Testing preferences in this population could be explored. Some men who have sex with men may prefer home- or venue-based testing or testing in general practice. Opt-out HIV testing could also be explored in sexual health settings with populations of men who have sex with men (who are at higher risk than the general adult population) (Yang et al., 2014).

Future research could also explore patients' experiences after testing positive for HIV through opt-out testing. The present research did not aim to examine this issue, but evidence suggests that HIV-related stigma remains a problem. In future studies, patients could be interviewed about their experiences with stigma after opt-out HIV testing, possibly in comparison to stigma experienced after opt-in testing. Patient experiences could inform future recommendations about post-test counselling and support. There was no consensus in the research that opt-out HIV testing caused a different degree of emotional stress than opt-in testing, but it could be considered for future research.

Cost-effectiveness of opt-out HIV testing needs to be studied in Australian health care settings. Several participants in the qualitative study stated that opt-out HIV testing would be too expensive, suggesting that cost may influence health care providers' decision to perform HIV testing. Other participants believed that the cost of HIV tests was not a barrier. Numerous international studies of EDs, hospital wards and other settings have found opt-out HIV testing to be cost-effective (Farnham, 2008; Lucas & Armbruster, 2013). Only one cost-modelling study from Australia (which referred to antenatal opt-out HIV testing) was discovered (Graves, Walker, McDonald, Kaldor, & Ziegler, 2004). Although this study found that opt-out HIV testing in antenatal settings was cost-effective, cost-effectiveness in Australian general practice is not known. Further research could identify the most cost-effective HIV testing practices for Australia.

Conclusion

The research in this thesis was guided by the Implementation Science process,

translating international evidence about opt-out HIV testing into an Australian setting for the first time. Presented as a series of chapters and publications, the research was guided by the Implementation Science concepts of needs assessment, planning, feasibility studies, and evaluation. Health care services that have not considered opt-out HIV testing now have evidence that the approach may be acceptable to health care providers and easily implemented. Opt-out HIV testing programs would need to be tailored to each organisation; the novel theoretical framework created for this thesis could provide a starting point.

The research identified the need for health care providers to be educated about the use of defaults in decision-making and preventing classification errors, but this education was not a barrier to the opt-out HIV testing program. The Homeless Healthcare Linkage to Care Protocol developed for this study for HIV-positive patients could be adapted to different health services. Using defaults (as per Behavioural Economics), the opt-out approach could be expanded to conditions that are more common than HIV, like depression, chlamydia or hepatitis C.

This thesis is the first exploratory study of opt-out HIV testing in a primary health care service in Western Australia. Literature reviews explored the previous research on opt-out HIV testing outside of Australia, providing context for the approach. Evidence about increasing HIV diagnoses in Australia offered a rationale for a possible change in HIV testing practice.

Attitudes and *Systems* were the main themes arising from the systematic review and re-emerged in the findings and theoretical analysis. Health care providers' beliefs about HIV testing were dichotomous: HIV testing should be treated as a normal practice (with an opt-out approach) or an exceptional practice (through the usual method of risk factor-based testing). Insights from this qualitative study led to the development of a comprehensive theoretical framework for opt-out HIV testing that was used in subsequent qualitative data analysis.

These preliminary studies culminated in the final prospective study of opt-out HIV testing at Homeless Healthcare. Health care providers found the opt-out approach to be feasible and acceptable, no adverse events occurred, and few patients opted out. Findings from this thesis have established an initial evidence base to guide further development of opt-out testing programs, inform health policy, and improve patient health.

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Appendix 1 Participant information sheet for the qualitative study (Leidel et al., *BMC Public Health*)

Study title: An exploratory study of health care providers' acceptance of opt-out HIV testing in Western Australia

RESEARCH TEAM

Ms Stacy Leidel, Lecturer & Nurse Practitioner, Curtin University School of Nursing and Midwifery

Dr Ruth McConigley, Senior Lecturer, Curtin University School of Nursing and Midwifery

Professor Duncan Boldy, Research Advisor, Curtin University School of Nursing and Midwifery

Dr Sonya Girdler, Senior Lecturer, Curtin University School of Occupational Therapy and Social Work

PROJECT INFORMATION

What will I have to do?

Our team would like to ask you about your views and practices related to HIV testing. You may also be asked to nominate colleagues who would be interested in participating. You will be asked to sign a consent form before the interview. Participation is strictly voluntary and you are welcome to withdraw at any time during the research. Being a participant will not have any negative consequences.

The interview will be audio-recorded, transcribed, then analysed and written up as a report for publication. The findings will be published in professional journals but will not contain any identifying information.

Will I be paid to participate in the study?

You will not be paid to participate in this study.

Are there any risks involved?

There are no risks involved with participation in this project.

What if I need more information?

If you have any questions about the study please contact Stacy Leidel at *stacy.leidel@curtin.edu.au*

Queries or complaints?

This project has been approved by the Curtin University Human Research Ethics Committee, approval number SONM12-2014.

If you wish to make a complaint on ethical grounds, please contact the Curtin University Human Research Ethics Committee (Secretary) by phone on 9266 2784 or by email to hrec@curtin.edu.au.

Written complaints can be mailed to: C/- Office of Research and Development, Curtin University, GPO Box U1987, Perth WA 6845.

Appendix 2 Participant information sheet for mixed-methods study (Leidel et al., *Australian Journal of Primary Health*)

Study title: An exploratory study of health care providers' acceptance of opt-out HIV testing in Western Australia

RESEARCH TEAM

Ms Stacy Leidel, Nurse Practitioner, PhD Candidate, Curtin University School of Nursing and Midwifery

Dr Ruth McConigley, Senior Lecturer, Curtin University School of Nursing and Midwifery

Professor Duncan Boldy, Research Advisor, Curtin University School of Nursing and Midwifery

Associate Professor Sonya Girdler, Curtin University School of Occupational Therapy and Social Work

Dr Sally Wilson, Adjunct Faculty, Curtin University School of Nursing and Midwifery

PROJECT INFORMATION

What will I have to do?

In this study we will ask you to implement opt-out HIV testing for all patients who are having pathology tests at Mobile GP clinics for a period of 12 months. Opt-out HIV testing is when you tell the patient that you will perform the HIV test unless he or she declines. Before we implement this change in practice, we will ask you to attend an educational session about this project at a regular staff meeting. We would appreciate your input into the protocol development at this stage, but you are not required to be involved. You will be asked to sign a consent form prior to participation. We will not keep any identifying information about you.

Once the protocol is developed, we will commence opt-out HIV testing. You are not required to participate in this phase of the research and will experience no negative consequence for not participating. If you choose to participate, you will perform an HIV test on all patients having routine blood tests unless they decline. You would say something like this to your patients: "We are testing all patients for HIV if they are having pathology tests, is that all right with you?" You would then proceed with pre-test counselling and informed consent as per your current HIV testing practice. You or another staff member would then

draw the blood sample and send it to the laboratory according to the usual procedure for pathology tests. Follow-up of test results and health department notification in case of a positive result would continue to be your responsibility.

An adverse event protocol has been developed with input from the Department of Clinical Immunology at Royal Perth Hospital to assist you in the event of a positive HIV test. If this occurs, you will liaise with the RPH clinical nurse and social worker to ensure that the patient is connected to HIV services in a timely manner. Our team is available to you should you have any concerns or require further support during the project.

After the project period, our team would like to ask you about your experience with opt-out HIV testing. We would also like to discuss things that facilitated or impeded this change in clinical practice. You will be asked to sign a consent form before the interview. Participation is strictly voluntary and you are welcome to withdraw at any time during the research. Being a participant will not have any negative consequences.

The interview will be audio-recorded, transcribed, then analysed and written up as a report for publication. The findings will be published in professional journals but will not contain any identifying information.

Will I be paid to participate in the study?

You will not be paid to participate in this study.

Are there any risks involved?

There are no risks involved with participation in this project.

What if I need more information?

If you have any questions about the study please contact Stacy Leidel at *stacy.leidel@student.curtin.edu.au*

Queries or complaints?

This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR **4877**). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth, 6845 or by telephoning 9266 2784 or by emailing *hrec@curtin.edu.au*

Appendix 3 Consent form for participants for the qualitative study (Leidel et al., *BMC Public Health*) and the mixed-methods study (Leidel et al., *Australian Journal of Primary Health*)

CONSENT FORM FOR PARTICIPANTS

Study title: An exploratory study of opt-out HIV testing in Western Australia

I have been given clear, written information about this research project and have been given time to consider whether or not I wish to take part.

I understand and accept the nature of the project, which has been explained to my satisfaction.

I understand that my interview will be audio-taped and transcribed.

I know that my participation in this project is strictly voluntary. I know that I have the right to withdraw at any time.

If I have any questions about the project or about being a participant, I can call Stacy Leidel on 0430647081 or email stacy.leidel@student.curtin.edu.au.

I know that I can contact the Research Ethics Officer at Curtin University on (08)9266 2784 if I wish to discuss any aspects of the program on a confidential basis.

I agree to participate in this project. I have been assured that my identity will not be revealed while the program is being conducted or when the program is published.

Participant's Name	Participant's Signature
Researcher's Name	Researcher's Signature

Date _____

Please keep a copy of this form for your records.

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Our Ref: KB/CAIC/P9293
5th December 2016

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Karin Beesley
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Expected completion date	Dec 2016
Expected size (number of pages)	200
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Appendix 7 Ethics approval for qualitative study (Leidel et al., 2015, *BMC Public Health*)

Curtin University

Memorandum

To	Ms Stacy Leidel, Nursing
From	Professor Peter O'Leary, Chair Human Research Ethics Committee
Subject	Protocol Approval Application 4877
Date	15 December 2014
Copy	Dr Ruth McConigley, Nursing Dr Sonya Girdler, Nursing Professor Duncan Boldy, Nursing Dr Sally Wilson, Nursing

Office of Research and Development
Human Research Ethics Committee

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Committee (HREC) for the project titled "*An exploratory study of health care providers' acceptance of opt-out HIV testing in Western Australia*". Your application has been reviewed by the HREC will be **approved subject to** the conditions detailed below:

1. Provide a definition of 'opt out' testing in the participant information sheet please clarify how this approach links to the methodology.
2. Please provide a one page summary, on what the project involves, the action that will be taken and the outcome.
3. Justify the sample size.
4. Recruitment – address potential for coercion between the recruiter and participant.
5. The Committee waives the consent in accordance with section 95A of the privacy act.

Please do not commence your research until your response to the above conditions has been approved and final clearance has been granted by the Human Research Ethics Committee.

Please note the following:

- Reference Number: **4877.** *Please quote this number in any future correspondence.*
- The following standard statement **must be** included in the information sheet to participants:

  *This study has been approved by the Curtin University Human Research Ethics Committee (Approval Number HR**xxxx**). The Committee is comprised of members of the public, academics, lawyers, doctors and pastoral carers. If needed, verification of approval can be obtained either by writing to the Curtin University Human Research Ethics Committee, c/- Office of Research and Development, Curtin University, GPO Box U1987, Perth 6845 or by telephoning 9266 9223 or by emailing hrec@curtin.edu.au.*

- It is the policy of the HREC to conduct random audits on a percentage of approved projects. These audits may be conducted at any time after the project starts. In cases where the HREC considers that there may be a risk of adverse events, or where participants may be especially vulnerable, the HREC may request the chief investigator to provide an outcomes report, including information on follow-up of participants.

Yours sincerely

Professor Peter O'Leary
Chair Human Research Ethics Committee

Appendix 8 Ethics approval for mixed-methods study (Leidel et al., 2017, *Australian Journal of Primary Health*)

MEMORANDUM

Curtin University

To:	Ms Stacy Leidel Nursing
CC:	
From	Professor Peter O'Leary, Chair HREC
Subject	Ethics approval Approval number: HR28/2015
Date	17-Feb-15

Office of Research and Development
Human Research Ethics Office

TELEPHONE 9266 2784
FACSIMILE 9266 3793
EMAIL hrec@curtin.edu.au

Thank you for your application submitted to the Human Research Ethics Office for the project: 4877

An exploratory study of health care providers' acceptance of opt-out HIV testing in Western Australia

Your application was reviewed by Human Research Ethics Committee at Curtin University at their meeting on the 9/12/2014

Thankyou for providing the additional information requested by the Human Research Ethics Committee. The information you provided was satisfactory and your proposal is now approved.

Please note the following conditions of approval:

1. Approval is granted for a period of four years from **17-Feb-15** to **17-Feb-19**
2. Research must be conducted as stated in the approved protocol.
3. Any amendments to the approved protocol must be approved by the Ethics Office.
4. An annual progress report must be submitted to the Ethics Office annually, on the anniversary of approval.
5. All adverse events must be reported to the Ethics Office.
6. A completion report must be submitted to the Ethics Office on completion of the project.
7. Data must be stored in accordance with WAUSDA and Curtin University policy.
8. The Ethics Office may conduct a randomly identified audit of a proportion of research projects approved by the HREC.

Should you have any queries about the consideration of your project please contact the Ethics Support Officer for your faculty, or the Ethics Office at hrec@curtin.edu.au or on 9266 2784. All human research ethics forms and guidelines are available on the ethics website.

Yours sincerely,

Professor Peter O'Leary
Chair, Human Research Ethics Committee

Appendix 9 Letter of support from Homeless Healthcare for ethics application

8 Cambridge Street West Leederville WA 6007
PO Box 1424 West Leederville WA 6901
P: (08) 6260 2092 F: (08) 9381 8903
TF: 1800 982 402
E: generalmail@homelesshealthcare.org.au
W: www.homelesshealthcare.org.au
ABN: 64 129 336 803

14th June 2015

Dear Human Research Ethics Committee,

We are aware that Ms Stacy Leidel will be conducting a patient survey as part of the project "An exploratory study of health care providers' views on opt-out HIV testing in Western Australia." We fully support this survey and our staff are happy to be involved.

Regards

Dr Andrew Davies MBBS FRACGP
Medical Director
Homeless Healthcare (Mobile GP)

All Donations $2 and over are tax deductible

Appendix 10 Linkage to care protocol for mixed-methods study

Opt-out HIV testing program at Homeless Healthcare: Linkage to care background and protocol

This research project involves a trial of opt-out HIV testing in a general practice. Unlike traditional HIV testing (which is based on a patient's request, risk factors, or clinical indications), opt-out testing is performed unless the patient declines the test. This normalises and de-stigmatises HIV testing by putting it on par with other treatable, chronic diseases. Prompt diagnosis of the infection is important because early HIV treatment has been shown to stop immune dysfunction, and people with HIV who engage with care can now live a normal or near-normal life span. To our knowledge, opt-out HIV testing in Australian GP practices has not yet been formally evaluated.

In this project, we will implement opt-out HIV testing at Homeless Healthcare, a primary care service for homeless and marginalised people. Our aims are 1) to explore the effect of the opt-out approach on testing rates and 2) to explore the acceptability and feasibility of opt-out HIV testing from the health care providers' point of view. The research will commence in April 2015 and is expected to continue for 12 months.

Although the overall prevalence of HIV in Australia is low, there is a chance that a patient could test positive for HIV during the study period. If this occurs, we will follow this protocol which has been developed by a multidisciplinary, collaborative team that includes Homeless Healthcare staff and HIV specialists. If an HIV-positive result occurs, Homeless Healthcare staff will immediately contact the Nurse Practitioner and Social Worker from the hospital HIV Medicine service, who are experienced in discussing HIV-positive results with patients. Homeless Healthcare staff will attempt to contact the patient within 24 hours after receipt of results from the laboratory. The patient will be asked to present to the Homeless Healthcare main office or to a drop-in clinic. Upon arrival to Homeless Healthcare, the patient will be escorted to the HIV Medicine service by a Homeless Healthcare RN. The HIV Nurse Practitioner and/or Social Worker will then discuss the test results and treatment plan with the patient. Alternatively, the Nurse Practitioner and/or Social Worker will come to the Homeless Healthcare drop-in clinic to meet with the patient, nurse and GP. This referral pathway provides disclosure of HIV-positive results in a caring and confidential way, connecting patients with treatment and social assistance without delay.

This research has been granted ethics approval (#4877) from the Curtin University Human Research Ethics Committee.